Ex. 21

Rebecca Gibson

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Monday, September 21, 2020 10:13 AM
To: Kandy Downs; Mercedes Livingston; Brook Jackson
Cc: Marnie Fisher; Kristi Raney; Katie Buchanan
Subject: RE: Daily Status Calls Updates and Action Items
Attachments: Daily Status Updates 9.19.2020.docx

Sorry I missed the last few minutes of the call. Please see attached.

Thanks,

Olivia Ray
Managing Member, Executive Director

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m: 214-394-0772
e: oliviaray@ventaviaresearch.com

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From: Olivia Ray
Sent: Friday, September 18, 2020 8:54 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Olivia Ray
Managing Member, Executive Director

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From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Thursday, September 17, 2020 5:11 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Will do.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

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From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Thursday, September 17, 2020 5:08 PM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: Re: Daily Status Calls Updates and Action Items

Kandy, to be clear, we want the RD's doing weekly or bi weekly touch points with the PI's. This is to check on the SOM's, site leads, staff, etc.

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From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Thursday, September 17, 2020 5:01:12 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Kandy

- QC both unblinded logs at KEL and FW FW done 9/17 Keller 9/18 to be completed.
- **Get ARL's screening visits canceled so Becca can immediately QC Keller Jennifer had 1 only visit-Becca sent to Keller**
- **Get Plano's visits handled by Precilia so Jill can immediately QC Keller- Jill had Dr's appt for new baby today-tomorrow going to Keller.**
- Check with William: done

  - FDA training
  - Should HOU stop enrolling, ask William, please done-and done

- Put a plan in place to schedule weekly touchpoints with your PI's my SOM"s do this, for Plano and Houston. Alma does Burleson/I do Dallas/Arlington.
- Talk with JP done see the email.
  - What did she mean that "Ventavia is going to get what's coming to them"? she stated never said this
    - Let him know how concerned Dr. B is about that Dr B informed and see my email
  - Go over Peppler's concerns-comments about being unhappy, unsupported, etc. Peppler email reviewed with Jennifer.
  - Go over professionalism, growth, examples that have been given done- are we writing her up via verbal? Written? All three issues together? Or separately?
  - Have KB as a witness and make sure this convo is all documented and sent to us so we can make an informed decision (write up vs termination) done

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

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From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Thursday, September 17, 2020 9:19 AM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Olivia Ray
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From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Wednesday, September 16, 2020 5:13 PM
To: Brook Jackson <bjackson@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Mercedes

- Get references for Tiara Done- she sent me three from Covance of people in three different positions (which is where all her experience is from)
    - I left a message for 2
    - Talked to the third one and she gave a glowing review. She said Tiara was the first non-RN to have an Operations Manager role. Covance at one point only allowed RNs as Operations Managers but when they opened it up to other, Tiara was the first to be promoted and to the Operations Manager of the morning shift which is the busiest shifts
    - I will try the other two again tomorrow if they don't call back tonight.
    - If good, then get a call with Medix

Mercedes Livingston, CCRC
Chief Operating Officer

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From: Brook Jackson <bjackson@ventaviaresearch.com>
Sent: Wednesday, September 16, 2020 4:01 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>
Cc: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: Re: Daily Status Calls Updates and Action Items

Απολογιεσ μψ ρεσπονσεσ αρε νοτ ιν □ρεδ□; ωορκινγ φρομ πηονε το χομπλετε τηισ τοδα ψ. Χομπυτερ ισσυεσ αγιν. Ωορκινγ ωιτη θερρεδ. Τηανκσ!

- □ Make sure Keller and FW have the Firecrest amendment 6 training completed by this morning - Almost there - will be done before EOB
- □ Speak to Jaz and have her go to Chrystal about communication with calling pts - Pending
- □ Speak to Jen Vasilio about overseeing Chrystal - Pending
- □ Continue to monitor recruitment efforts for FW and KEL-COVID - ongoing

On Sep 16, 2020, at 8:54 AM, Olivia Ray <oliviaray@ventaviaresearch.com> wrote:

Olivia Ray <image002.png>
Managing Member, Executive Director

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<image003.png>

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<image004.png>

<image007.png>

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Tuesday, September 15, 2020 4:50 PM
To: Brook Jackson <bjackson@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Mercedes

- Check with Kate on Amend. 6 ICF Confirmed all sites have this and have implemented it
- Give directive to sites and recruiters if we can start enrolling 16 and 17 yr olds- all sites know but will send a email so it's in writing
    - ICF IRB approved and received by sites received
    - Amend 6 firecrest training completed- notified sites to complete, protocol sent through Complion for signing off for training
- Follow up with reg person about hours and schedule – pending response

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Chief Operating Officer

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Fax Number: 817-394-1901
Email: mercedeslivingston@ventaviaresearch.com



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From: Brook Jackson <bjackson@ventaviaresearch.com>
Sent: Tuesday, September 15, 2020 4:38 PM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Marnie/Brook

- Keep a close eye on Katie/Keller's enrollment numbers, she needs to continue to try and schedule the full 60 for the week. If she's having a challenge with less CRC's, she needs to loop us in before Chrystal decides to stop scheduling patients. We are currently at 42 scheduled for the week. We have open appt times each day that Lanie is working to fill, including a quick Saturday clinic from 7:30-8:45. Dr. Fuller wanted to be done with clinic on Sat. by 9:15.
- Work with Chrystal this week to get numbers up, check on CC list for 16 and 17 yr olds (or waiting list?) WORKING ON
- Focus on the recruitment this week for FW and KEL (Covid) – KEL is working on 2nd attempt emails, but have completed ThreeWire 2nd attempt calls; Lanie is also making calls right now to confirm 16Sep appts. For those she is able to reach she is asking if they have any potential referrals including those 16+.
- Help with Alma exit plan - MARNIE

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Tuesday, September 15, 2020 4:05 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Marnie/Brook

- Keep a close eye on Katie/Keller's enrollment numbers, she needs to continue to try and schedule the full 60 for the week. If she's having a challenge with less CRC's, she needs to loop us in before Chrystal decides to stop scheduling patients. BROOK
- Work with Chrystal this week to get numbers up, check on CC list for 16 and 17 yr olds (or waiting list?) WORKING ON

- Focus on the recruitment this week for FW and KEL (Covid) WORKING ON
- Help with Alma exit plan- TALKING TO ALMA NOW- she's coming down to the conference room to discuss options

Pending from yesterday:

- Get with Angela about adding onboarding newhire for the next two weeks, OT approved if needed (submit to Marnie or Mer for approval??) – DONE- Angela is going to send me a list of all the tasks she's working on and in the meantime, meeting with Katie, I belive tomorrow, to discuss what Katie needs her to do. Angela is willing to help but worried that she's going to drop the ball on all her other responsibilities, FYI. I told her not to worry about this, that we understand it will pull her from other duties.

Regards,
Marnie

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Tuesday, September 15, 2020 9:31 AM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Olivia Ray <image016.png>
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<image003.png>

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<image017.png>

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Monday, September 14, 2020 9:31 PM
To: Brook Jackson <bjackson@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Marnie

Can you please get with Angela first thing (after our call in the morning) about taking over onboarding from Katie B?

We have Ruth and Jessica Mendez that need to be onboarded and they need to get moving quickly. I have multiple calls set up tomorrow so I need you to call Angela and get with her on this.

I think she has been working some with Katie on onboarding, so it should be a quick/smooth transition.

Regards,

Mercedes Livingston, CCRC
Chief Operating Officer

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<image014.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

<image015.jpg>

From: Brook Jackson <bjackson@ventaviaresearch.com>
Sent: Monday, September 14, 2020 4:03 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Marnie/Brook
14Sep2020

Can you have J. Valo work in GRA on Wednesday – DONE
Get with Katie Buchanan to add J.Valo to timeco – DONE; Marnie sent email to Katie Buchanan this am.
Jailyn-help email, make sure it was dealt with (with Jen Vasilo), please get Jailyn in a better place (documented games plan to get things distributed) – Per Jen V., they discussed action plan that will be documented in writing. Email pending from Jen V.
Let sites know to reach out to James/Burt when they need help filing so they can knock it out – Done.
Reach out to Jen Vasilo about Jerred's load and let him know about Katie Buchanan pulling him to work with her (newsletter, bamboo HR/timekeeping system, etc.) - DONE
Identify a scanner – DONE
Get with Angela about adding onboarding newhire for the next two weeks, OT approved if needed (submit to Marnie or Mer for approval??) - pending
Stay on your SOM's to get the missing certifications, PI/SubI stuff done **this week –** In progress

---

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Monday, September 14, 2020 1:04 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

9/14
Kandy

- Let sites know to reach out to James/Burt when they need help filing so they can knock it out email sent.
- Identify a scanner. I sent out an email to Ventavia.
- Get Univision ad ran today. I have sent email, working on getting out by Wed/Thursday.
- Get in touch with Christine to see if Lizatte can call Syan Rhodes about a follow-up story, and then all other HOU sites done
- Stay on your SOM's to get the missing certifications, PI/SubI stuff done **this week done**
- Talk to Christine about extending Tony's contract if he can done and extended till he gets an offer or no longer needed.
- Talk to Becca about staying in ARL for right now, and have her go to Dallas one day this week to QC done-she has a 2 weeks sch for Arlington, adding QC for Dallas in there as well. She is out next week for a couple of PTO days.

9/11
Kandy

- Precillia review to Mer Jill sent the revision
- Tell Christine to make second interview rounds and narrow it down done on 9/11 via phone

- Talk to Mark about helping with reg done on 9/11 via phone and email.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

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<image011.png>
<image014.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Monday, September 14, 2020 9:32 AM
To: Kristi Raney <kristiraney@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Olivia Ray <image016.png>
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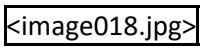
From: Kristi Raney <kristiraney@ventaviaresearch.com>
Sent: Saturday, September 12, 2020 1:18 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: Re: Daily Status Calls Updates and Action Items

I'm not sure if this was ever answered, but there was a question about the PM role being a promotion for JV. It is not. I do understand there are some SOMs going into this role, but it's a new position...and it's not a promotion for JV. It's still a lateral move for her. She was managing MRSV medical records and now she's managing more (old studies).

We can discuss further on Monday, if need be.

Kristi Raney
Managing Member,
Executive Director



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On Sep 10, 2020, at 4:01 PM, Kandy Downs <kdowns@ventaviaresearch.com> wrote:

Kandy

- QC MAT RSV charts in FW They were already done-
- Continue reviewing resumes and will forward those recently reviewed to Kristi/Mercedes already forwarded

Completed onboarding/New Hire training with Becca S and Brook. Worked on emails/ Review for Jennifer completed.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

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<image002.png>
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From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Thursday, September 10, 2020 10:57 AM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Sorry, with attachment.

Regards,
Marnie

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Thursday, September 10, 2020 10:16 AM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Call notes from this morning.

Regards,
Marnie

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Wednesday, September 9, 2020 9:16 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Call notes from this morning.

Brook- We all have alarms set at 4:00 on our phones as a reminder to send a follow-up on our to-do list from the morning call. We copy and paste our section of to-do in this email chain and in red next to the time we write out the outcome.

I put items under you/Marnie today. Please shadow her on all her action items and if there are any you can take over (after introducing yourself to those involved in the action item) you can do that as well.

All responses stay in this email chain so it's easy to reference from one day to the next.

Regards,

Mercedes

Mercedes Livingston, CCRC
Chief Operating Officer

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From: Mercedes Livingston
Sent: Tuesday, September 8, 2020 6:30 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Kandy

To confirm, are you saying you already did Cristina's review with her? If not, please don't I want to review it first (I'm working through emails). Also, you will want to have Katie B on the phone when you do the review with her. We want to have a witness on all reviews/disciplinary/coaching sessions.

Regards,

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
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Cell: 817-845-3824
Fax Number: 817-394-1901
Email: mercedeslivingston@ventaviaresearch.com

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Tuesday, September 8, 2020 5:11 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Kandy

- Work on Univision thing-have spoken to 3 different people that are working up numbers and such. The attachment that I got was for COMCAST- and is a joke. So working with really Univision. Will send emails as they come for approval and cost
- Get reviews to Mercedes-send Cristina's and completed today. Almost finished with Jennifer P having Becca help me since we both have been working with her.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

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Email: kdowns@ventaviaresearch.com

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From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Tuesday, September 8, 2020 8:23 AM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

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From: Olivia Ray
Sent: Friday, September 4, 2020 12:07 PM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Sorry I forgot to send this out this morning!

Olivia Ray 
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

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From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Thursday, September 3, 2020 4:47 PM
To: Kristi Raney <kristiraney@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Mercedes

- Get Angela ready to go remote next week- done
- Get resume from Kati Dykes to call and interview- LM, phone went straight to VM

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
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Ft. Worth, Tx 76104
Office: 817-348-0228
Cell: 817-845-3824
Fax Number: 817-394-1901
Email: mercedeslivingston@ventaviaresearch.com

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https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

<image003.jpg>

From: Mercedes Livingston
Sent: Thursday, September 3, 2020 4:43 PM
To: Kristi Raney <kristiraney@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>

Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Yes, Becca trained her on it this morning. JP followed up in a text to me confirming.

Regards,

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
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Ft. Worth, Tx 76104
Office: 817-348-0228
Cell: 817-845-3824
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Email: mercedeslivingston@ventaviaresearch.com

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https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

<image003.jpg>

From: Kristi Raney <kristiraney@ventaviaresearch.com>
Sent: Thursday, September 3, 2020 4:15 PM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: Re: Daily Status Calls Updates and Action Items-Kandy

Mer, was your last email addressing this...

Pending visits in CC in ARL the last couple of days Sent a request to Jennifer to either complete them or move them over. I can't move them when I don't know what is going on with them. Also, need Kandy to be on top of this with Jennifer.

Can Becca help with this? Maybe she can 1) help get it caught up 2) make sure JP understands and doesn't have any questions

Just want to make sure this got addressed (either Becca helping or JP getting it done).

Thanks,

Kristi Raney
Managing Member, Executive Director

Ventavia Research Group

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817-394-1901 eFax

214-208-0390 Cell



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From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Wednesday, September 2, 2020 9:18 PM
To: Kristi Raney <kristiraney@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Jennifer actually called me when she got my email. She hasn't been using the check-in check out page to look at these. So, I showed her where I was looking and now she knows. She is going to call me tomorrow when she is ready to complete her diary check visits so I can show her how to do them from the check-in check-out page.

Thanks,

Mercedes Livingston, CCRC
Chief Operating Officer

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Cell: 817-845-3824
Fax Number: 817-394-1901
Email: mercedeslivingston@ventaviaresearch.com

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https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

<image003.jpg>

From: Kristi Raney <kristiraney@ventaviaresearch.com>
Sent: Wednesday, September 2, 2020 5:10 PM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: Re: Daily Status Calls Updates and Action Items-Kandy

Pending visits in CC in ARL the last couple of days Sent a request to Jennifer to either complete them or move them over. I can't move them when I don't know what is going on with them. Also, need Kandy to be on top of this with Jennifer.

Can Becca help with this? Maybe she can 1) help get it caught up 2) make sure JP understands and doesn't have any questions

Kristi Raney
Managing Member, Executive Director

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214-208-0390 Cell

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<image011.png>
https://www.ventaviaresearch.com/ http://www.platinum-research.net/

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Wednesday, September 2, 2020 5:03 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Mercedes

- Talk with William about his recommendations for QC employees requested from William. Directed him to do the first interview and send to me for second interviews
- Log into Firecrest to see if we have a radio ad already approved by Pfizer Not in Firecrest, pending reply from Arturo
- Talk to Haily, Elyza, and Jessica today so we can make a decision on Erin LM for Elyza and Jessica. Haily doesn't have any experience regarding Clinical Research that would apply to step into a CRC role at any site.
- Oversee the Inv onboarding email ongoing
- Pending visits in CC in ARL the last couple of days Sent a request to Jennifer to either complete them or move them over. I can't move them when I don't know what is going on with them. Also, need Kandy to be on top of this with Jennifer.
- Send an email chain to get status update at end of each day, how many they got to, etc. Any glaring findings? Set an alarm. Email sent

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group

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Email: mercedeslivingston@ventaviaresearch.com

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https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

<image003.jpg>

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Wednesday, September 2, 2020 9:29 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Olivia Ray <image004.png>
Managing Member, Executive Director

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t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

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www.ventaviaresearch.com

<image006.png>

<image007.png>

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Tuesday, September 1, 2020 5:02 PM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>
Subject: FW: Daily Status Calls Updates and Action Items-Kandy

Sorry only sent to Olivia

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
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Email: kdowns@ventaviaresearch.com

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<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Kandy Downs
Sent: Tuesday, September 1, 2020 5:01 PM
To: 'Olivia Ray' <oliviaray@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Kandy

- Look at resumes for CRC's for almost all sites done- see the attached resumes I reviewed that I thought would be good fits. There were no notes with these.

I have tagged them all via Indeed message to see if they are still interested in the positions before we start calling them.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

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<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Tuesday, September 1, 2020 8:53 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Olivia Ray <image004.png>
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e: oliviaray@ventaviaresearch.com

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<image006.png>

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From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Monday, August 31, 2020 3:56 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

- Have Cordy do the first vaccine on the phone with her Done. And rechecked when onsite.
- Dallas-IRB documentation emails Shannon informed and Precilia to work with Shannon
- Keller phlebotomist email-follow up with Katie (Cara Lopez-rate) Katie reminded, to contact her.
- Let Olivia know if we need to activate HOU ad tonight
- Help with Katie B email re: investigators work in progress- to be honest, I have only reached out to Dallas. Been busy with Keller.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

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From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Monday, August 31, 2020 8:46 AM
To: Kristi Raney <kristiraney@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Olivia Ray <image004.png>
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m: 214-394-0772
e: oliviaray@ventaviaresearch.com

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<image006.png>

<image007.png>

From: Kristi Raney <kristiraney@ventaviaresearch.com>
Sent: Friday, August 28, 2020 10:21 AM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Subject: Re: Daily Status Calls Updates and Action Items- Kandy

I agree with what Olivia said. I actually feel like this was brought up a few weeks ago...that she had no training and has very little oversight bc she is the unblinded. I feel like that's when Kandy went over there a week or so ago and caught the Becca situation...but I thought part of our discussion was that she had no oversite and could be screwing up and no one know.

Maybe I thought this all though...and never actually said it out loud...idk.

So yeah, let's see who we could possibly get over there with her to start helping out on Monday. Otherwise, something bad is going to happen with her.

Kristi Raney
Managing Member, Executive Director

Ventavia Research Group

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Fort Worth, TX 76104

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817-394-1901 eFax

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From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Friday, August 28, 2020 10:11 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

I spoke with Kandy and she is heading to Kel this afternoon to help Cordy get items corrected and clarified on her logs and get with the unblinded CRA to address any items she has.

Kandy, please let us know how this afternoon goes. As it stands now, I'm not comfortable with Cordy being the only unblinded vaccinator for this trial.

- Is there an experienced unblinded for this trial that can go work alongside her starting Monday, until we feel comfortable she knows what she is doing?

Thanks,

Olivia Ray <image014.png>
Managing Member, Executive Director

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m: 214-394-0772
e: oliviaray@ventaviaresearch.com

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<image006.png>

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From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Friday, August 28, 2020 9:58 AM
To: Olivia Ray <oliviaray@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Morning;

See in purple my FUL to your blue. LOL

I also want you both to be aware that we (Keller site) unblinded received an email from the blinded CRA-there are a lot of concerns. I will try to address via remote if I can't, then I will have to go to Keller today to review and discuss with Cordy. It looks like CRA has tried to work with Cordy but not getting a resolution. But I will contact Cordy this morning, and I will see what I can do from Arlington.

See below.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
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Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

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From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Friday, August 28, 2020 7:54 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

I know we aren't having a call this morning due to Mer seeing a pt and me on the PSSV, but I wanted to address a couple of things. See in blue:

- Reach out to KB in KEL about EDC entry email sent to Mercedes- EDC good/Complion need helps-Katie B informed to have uploaded, and we can have Jerred remote file for them. Is Keller planning on working tomorrow to get Complion caught up? Unless I am missing something, this needs to be caught up before the week is over. When I spoke with Katie B yesterday, she stated that they were going to get uploaded by today. And have EDC updated daily I will reach back out today and see where they are.

- Reach out to Christine, Lizatte, Jill re new roles Discussed;

  Jill-location? Remote? Then maybe some travel sch. Salary increase? Or the same? Interested-timeframe of a switch? Kandy, see in the email I sent yesterday that answered the remote and onsite question. I copied and pasted below in case you need to touch base with Jill again with some of that information. Salary—we will get back to you on that. Timeframe—I feel like that depends on when Shannon and Christina are better trained and don't need PLA to lean on. I would suggest telling Jill in the meantime, to learn everything maternal while working in PLA, and how we have set it up this year. So she knows how to get the sites better prepared when GSK starts (pre-screening docs, etc.) Perfect.

  Lizatte- Is excited, and Christine is yes, this is so Lizatte. Both onboard with this laterally move.-? We will get back to you about lateral move vs. salary increase. I will need to schedule a time with Lizatte to train

her and go over her role. I will wait and do that once Pfizer enrollment has stopped—unless you think they can enroll without her? Right now, with 3 new hires being trained, Lizatte is needed. I am thinking the end of the COVID study.

Study Manager/Project Manager/Protocol Facilitator Role (whatever we decide) (How to present this role to Jill and Dana—we can hold off on Becca)

- Brand new role created for the company to ensure we are setting everyone up for success
- Mainly remote, with onsite visits during first days of enrollment to ensure accuracy of everything being followed
- Working in conjunction with the RD's to make each site/study successful
- Need for experienced CRC's who have been with VRG for a while who know our processes
- Critical position where planning, details, and follow-through are extremely important
- HUGE amount of trust will be placed in this person/position

Reviewed this with Jill-

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From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Thursday, August 27, 2020 4:51 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Mercedes

- Reach out to Erin re: medical records- According to Marnie's email this morning, she has already had this discussion with Erin, Kati D, and Jennifer V
- Go through Kate's email and reach out to Becca about source (Pfizer Mat RSV and COVID) Done. Kate sent Becca what she has (rough draft docs) and Becca said she would have RSV and COVID done by EOB tomorrow
- Kate-OT approved, talk to her about training William- Kate doesn't think she wants PTO. Her weekends are her time to decompress and destress for the anxiety of her weeks. I did instruct her to get with William (since source came off her and we are holding off on GSK reg packets) and Kate it to get with William and spend about an hour trying to loop him in.
- Final interview/vet Erin McLeod, approval to hire for FW, 57k I talked to Erin and I liked her. Seems eager to learn and very smart. Her research experience is in non-industry trials (derm studies on makeup, lotion, hand soaps, baby wipes, et) so she would have a transition period to learning FDA regulated trials. I'm going to try and get to a few more that Jennifer has done first rounds on and then come back to her.

Mercedes Livingston, CCRC
Chief Operating Officer

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mercedeslivingston@ventaviaresearch.com

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<image002.png>
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From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Thursday, August 27, 2020 4:38 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Kandy
8/27

- Reach out to Christine, Lizatte, Jill re new roles Discussed;

  Jill-location? Remote? Then maybe some travel sch. Salary increase? Or the same? Interested-timeframe of a switch?

  Lizatte- Is excited, and Christine is yes, this is so Lizatte. Both onboard with this laterally move.-?

- Go to the sub-I mess of an email and handle Marnie's sites also so I tried, I will work on tomorrow. Needs more time than 1 day.
- Angi training for Pfizer mat RSV over the weekend done!
- Reach out to KB in KEL about EDC entry email sent to Mercedes- EDC good/Complion need helps-Katie B informed to have uploaded and we can have Jerred remote file for them.

8/26 missed couple yesterday

- Pending visits in CC-see Mer's email (DAL, ARL, HOU) was done yesterday.
- Call Kate and ask her to resubmit PSF for COVID-19 (from CC) ASAP I updated the form(learned how) and sent email Gabby. See the email (per Kate W help)
  - IRB approved autoimmune diseases, incl T1 diabetes (but this is incorrect and needs to be removed) removed- and #21 updated since 28 days have to be applied to this exclusion.
- Work with Chrystal to figure out how to identify and contact any subjects we inadvertently PS failed bc of T1 diabetes and re-PS for scheduling Chrystal has a list- and Pam already slacked. 27 subjects on the DNQ for various reasons-only 1 DM. RA subject to confirm about Immune meds.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

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From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Thursday, August 27, 2020 8:34 AM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Study Manager/Project Manager/Protocol Facilitator Role (whatever we decide) (How to present this role to Jill and Dana—we can hold off on Becca)

- Brand new role created for the company to ensure we are setting everyone up for success
- Mainly remote, with onsite visits during first days of enrollment to ensure accuracy of everything being followed
- Working in conjunction with the RD's to make each site/study successful
- Need for experienced CRC's who have been with VRG for a while who know our processes
- Critical position where planning, details, and follow-through are extremely important
- HUGE amount of trust will be placed in this person/position

Olivia Ray <image020.png>
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<image006.png>

<image015.png>

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Thursday, August 27, 2020 7:41 AM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

My apologies, I had this pulled up to send but didn't send. I'm out of the office today and tomorrow but will be available by phone if needed.

I'll send you a f/u on the discussions I had with staff changes as well.

Marnie

- Pending visits in CC-see Mer's email (DAL, ARL, HOU)- Kandy's sites, but noted and will f/u also if needed.
- Check on unblinded situation for KEL- Pending Jill/Precilia's training on Firecrest- both will help as back-up. Cordy will continue to use Gina as sign-off.
- Work with Jen Vascilio about Saturday clinic for covid-19 DONE- Jen is working on and will send f/u today.
- Need to make KEL and FW understand that in order to get the $500 stipend, they need to work whatever it takes (late nights and Sat clinics) to get close to their enrollment goal each week DONE

Regards,
Marnie

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Wednesday, August 26, 2020 8:58 AM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Olivia Ray <image016.png>
Managing Member, Executive Director

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From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Tuesday, August 25, 2020 4:46 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Mercedes

- Call Deedra and offer ARL- This is pending the presentation tomorrow, I believe
- Get with Marnie and decide who needs to get added to Keller PSSV- I will be on the call

Mercedes Livingston, CCRC
Chief Operating Officer

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Email: mercedeslivingston@ventaviaresearch.com

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<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

<image003.jpg>

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Tuesday, August 25, 2020 9:03 AM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Olivia Ray <image021.png>
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1307 8th Avenue Suite 202
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t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

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<image006.png>

<image022.png>

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Monday, August 24, 2020 11:46 PM
To: Kristi Raney <kristiraney@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

I apologize for the delay on this, we were short-handed today in FW and then I had our PSSV at 3, so I wasn't able to get to this on time.

- Check on PSSV time today for Novavax (make sure to mention access to minorities and healthcare workers), grab JV or Angela for any VRG specific questions **DONE**
- Offer the $500 weekly stipend to all FW clinic employees willing to work OT/Sat clinics to get these 60 in, manager needs to collect the employees' names and submit these stipends to payroll at each run, cc Kristi, Olivia, Mercedes, so payroll knows its legit **DONE**- communication sent, pending feedback.
- Thea-speak to her about urgent matters, she should have told us RIGHT way, we could have had all weekend to schedule and plan for this week. This is a HUGE deal. Verbal warning. Now we might have lost 20 pts for this week. This was hundreds of thousands of dollars on the line. If she emailed it on Friday, the email needs to be forwarded to us. I will send an email out, as directed below. I explained to Thea how critical this is and she stated she understood and will be sure to alert leadership immediately. She said she was following the chain of command by alerting Dana and then myself, but I reminded her to reference the Ops Manual for important communications- I pulled it out and we went over it together. **SEE ATTACHED** email from Arturo- he sent this last night.
- Get Janssen game plan going for season 2 participants (49 pts, 3 hours visits, starting Sep 7th?) **WORKING ON**- today I completed the updates for the IBC items they needed to be completed that were delayed- initially sent to Michelle. This took me more time than expected since I didn't have anything at my fingertips, but got it all figured out.
- Let your sites know, anything that would be printed and put in hard reg binder, needs to be uploaded to Complion **DONE**
- Pending visits in CC Aug 20th **DONE-** There are tons for FW today that didn't get completed- Dana stated that she instructed Thea and April to make sure they got done today because she was OOO today, but I just checked and none of them were done. Dana will get this done first thing in the morning. We only had 4 CRCs today and saw 27 patients in total.

Regards,
Marnie

From: Kristi Raney <kristiraney@ventaviaresearch.com>
Sent: Monday, August 24, 2020 12:42 PM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: Re: Daily Status Calls Updates and Action Items- Kandy

Marnie,

Thanks for digging in on this. I still don't think it's okay for Thea to hear that kind of SUPER important information and not relay it to leadership immediately.

I really expect this will never happen again. I would also appreciate you sending out an email to all sites and let them know that if a situation like this ever happens (increase in enrollment cap lifted) that they immediately notify leadership.

Thanks,

Kristi

Kristi Raney
Managing Member, Executive Director

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From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Monday, August 24, 2020 12:22 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>

Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

I wanted to touch base about this issue below with Thea- she said she hasn't received a confirmation email from Arturo yet, it was only a phone call Friday and he said we could "possibly" enroll 60- she left him a voicemail to follow-up with us ASAP by email.

Marnie

- Check on PSSV time today for Novavax (make sure to mention access to minorities and healthcare workers), grab JV or Angela for any VRG specific questions
- Offer the $500 weekly stipend to all FW clinic employees willing to work OT/Sat clinics to get these 60 in, manager needs to collect the employees' names and submit these stipends to payroll at each run, cc Kristi, Olivia, Mercedes, so payroll knows its legit
- Thea-speak to her about urgent matters, she should have told us RIGHT way, we could have had all weekend to schedule and plan for this week. This is a HUGE deal. Verbal warning. Now we might have lost 20 pts for this week. This was hundreds of thousands of dollars on the line. If she emailed it on Friday, the email needs to be forwarded to us.
- Get Janssen game plan going for season 2 participants (49 pts, 3 hours visits, starting Sep 7th?)
- Let your sites know, anything that would be printed and put in hard reg binder, needs to be uploaded to Complion

Pending visits in CC Aug 20th

Regards,
Marnie

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Monday, August 24, 2020 9:23 AM
To: Kristi Raney <kristiraney@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Olivia Ray <image016.png>
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e: oliviaray@ventaviaresearch.com

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From: Kristi Raney <kristiraney@ventaviaresearch.com>
Sent: Monday, August 24, 2020 5:52 AM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: Re: Daily Status Calls Updates and Action Items- Kandy

I'm a little concerned about the "restructure" statement. I don't feel HOU needs someone coming in and restructuring them. And I'm wondering how she even came up with that when she hasn't seen anything or how they function, etc.

I'm not sure I'm sold on this one. And she's too expensive.

Kristi Raney
Managing Member, Executive Director

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<image013.png>
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From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Friday, August 21, 2020 4:53 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

- Call HOU RD to see if interested in contract QC position, get rate, ask about travel to DFW if she were to get the RD position Reached out, and talked with Judy. She is at 60$ here, which is still $125K yearly. She is not interested in contract work-but will take an RD position with Houston and a Dallas(she has family up in the area) My only concern is that she and same Jennifer V stated was she would want to remake the system in Houston- instead of working with the status quo and making improvements she would want to restructure. But otherwise, she is great to talk with interaction was great. I called Judy to try and get a feel for her. I spoke with Kandy and got some feedback from her call and I understand she isn't wanting a contract QC position. I would like to talk to her and get a feel for her. I left a voicemail and followed up with an email to try and schedule a time to talk either Monday or Tuesday- Mer
- Get HOU to create a schedule for COVID enrollment I have asked Christine, they a lot of enrollment this afternoon, she is going to work on getting to us by tomorrow morning before 8 am.
- Create a site plan to recognize holes pending on with Marnie.

Mercedes Livingston, CCRC
Chief Operating Officer

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From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Thursday, August 20, 2020 5:25 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Kandy

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- Get HOU to create a schedule for COVID enrollment I have asked Christine, they a lot of enrollment this afternoon, she is going to work on getting to us by tomorrow morning before 8 am.
- Create a site plan to recognize holes pending on with Marnie.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

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1307 8th Ave Suite #202
Fort Worth, TX 76104

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eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

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<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Thursday, August 20, 2020 9:06 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Olivia Ray <image016.png>
Managing Member, Executive Director

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From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Wednesday, August 19, 2020 5:11 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>

Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Kandy

- Find an employee to hire to upload Complion for COVID-19 Christine husband offered/accepted, sending information to Katie for background and onboarding fast track (LOL Katie)
- Find or delegate someone to find a high-speed/high volume scanner to purchase for sites that need it Already talking with Jerred, pending more research should have more in the morning
- Finish write up and send to everyone for review Done-send at 5pm.
- Get with HOU regarding 5 pending visits in CC from 8/17 Christine aware, and will check in at 530pm

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

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Email: kdowns@ventaviaresearch.com

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<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Wednesday, August 19, 2020 2:27 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Sorry about that.

Olivia Ray <image016.png>
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e: oliviaray@ventaviaresearch.com

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<image026.png>

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Wednesday, August 19, 2020 2:19 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

So this attachment is for yesterday. Do we have today?

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

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Email: kdowns@ventaviaresearch.com

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https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Wednesday, August 19, 2020 9:09 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Olivia Ray <image016.png>
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e: oliviaray@ventaviaresearch.com

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<image006.png>

<image025.png>

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Tuesday, August 18, 2020 5:01 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

- Talk to your COVID sites. Yes, this was done with Houston.
    - As soon as they have a no show, call the recruiter and tell them to fill the spot

- Schedule 20 Mon and 20 Tues, and 8 pts for Wed (in case recruitment cannot replace N/S's on Mon/Tues) If we hit our 40 by Tues, then move Wed's 8 pts to the following week. Houston just increased to 80 per phone call
- Pull up CC and account how many are short Rudie is working on adding patients

- Pending visits in CC since 8/12. Yesterday, there are still 25 pending visits. If sites do not know how to complete these, reach out to Angela for guidance. Houston at 455pm had a total of 27- multiple ediaries, Visits 1 that are occurring, will have done by EOD-still enrolling COVID subjects

  Burleson had 3 spoke with Alma

  Dallas had 1-canceled enrollment from today.

- Talk to maternal calls, on-call phones need to be with them at all times. Mom's are starting to deliver. Patients, staff, doctors are to ONLY call on-call phone. Not personal phones! This was relayed via phone call, and an email sent.
- Think about Regional Director vs Support Specialist title, and who, internally, would be a good fit. So, I am still confused about what exactly this would mean to me directly. So I am the Regional Director-would I lose my title? Or would the Support specialist title be under me, and I would be relabeled?

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

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Email: kdowns@ventaviaresearch.com

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From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Tuesday, August 18, 2020 11:21 AM

To: Kandy Downs <kdowns@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Mercedes, please make sure you address Kandy's questions below from her previous email. And I HOPE the system doesn't prevent us from making up numbers from last week and then we don't run into this issue again, starting next week!

So, confirming that Keller needs only to get to 40 this week, and last 14 from last week, we can't enroll?

Same in Houston the 9 we thought to makeup, we have lost. So questions will the system prevent them from enrolling if they go over?

On the IP, so since the placebo is approx. 30, and the drug is approx. 20- - so you are stating 15 to 20 mins for both for IP prep time and then giving?

I just want to make sure I have the right mindset here.

Olivia Ray <image016.png>
Managing Member, Executive Director

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From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Monday, August 17, 2020 4:56 PM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>

Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

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From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Monday, August 17, 2020 4:27 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

847/2020 Action Items
Mercedes

- Confirm with Pfizer about what constitutes a week, can we get a head start on a Friday (as long as we don't go over 40 the following week), what is the window of IP
    - A week is Monday- Sunday
    - They are going to start capping each site for the next few weeks to randomizing 40 patients a week
    - This means, if we are short one week and only enroll 35 pts, we **CANNOT MAKE THOSE 5 UP THE FOLLOWING WEEK!** We lose those 5 pts.
    - We will start receiving larger shipments but we **CANNOT** enroll over 40 pts a week. The larger shipments are for the V1 and V2s that will start coming in.
    - It may be Sep before they look at raising anyone's drug supply or allowing for overage.
- Confirm with Pfizer that time IP needs to stay out and give proper directive to Marnie and Kandy, so they can let their unblinded staff know
    - This is what is in the IP manual in regards to thawing:
        - 8.4. In-Use Shelf Life and Storage Requirements for BNT162 Vaccine and Placebo Vials Vials of BNT162 Vaccine Concentrate Solution for Injection, 0.5 mg/mL must be stored in the freezer between -80 and -60ºC (-112 to -76ºF), protected from light and kept in the original packaging until ready for use in dose preparation. Allow all vials to thaw at room temperature (no more than 25 °C/ 77 °F) for **approximately 20 minutes** prior to dose preparation. When the contents of the vial are completely thawed, gently invert 5 times to mix thoroughly. Do not shake. If unused vials are left at room temperature for more than 2 hours they should be discarded. Minimize exposure of BNT162 Vaccine vials and prepared dosing solutions to room light during storage. Avoid exposure to direct sunlight and ultraviolet light. Dosing solutions can be prepared and handled in normal room light conditions. Placebo vials of 0.9% Sodium Chloride, USP (10 mL/vial) shall be stored at 20 to 25 °C (68 to 77 °F).
    - This is in regards to Placebo (pg 35):
        - In order to maintain the study blind, the label on the final prepared active and placebo dosing syringes must have a blinded product name (e.g. BNT162 Vaccine 10 mcg, 20 mcg, 30 mcg, or Placebo) as well as the same expiry date and time.
        - If preparing the placebo dose, please wait at least 30 minutes after dose preparation before delivering the final dosing syringe to the location of administration in order to maintain the study blind.

- Sponsor-provided occluding label must be applied to all prepared active and placebo dosing syringes to maintain the study blind. •
- A confirmation of study blind statement must be documented in the participant's source documents (see below) • Document all steps performed as indicated in the Preparation Record (Appendix 5, 6, or 7).

- So what it is saying is **study drug** should thaw for approximately 20 min, maybe more like 15 if being warmed in hands, etc. But, we can't just go and draw up Placebo and give it to the pt, if would be obviously. So, I think each unblinded needs to be made aware that the thawing time for the study drug is **APPROXIMATELY** 20 min. I would encourage them to get it to the 15 ish mark, and then draw up when it's totally thaw and then draw up placebo in around the same amount of time. What I don't want, is the study drug sitting in the room for 30 minutes with nothing happening. It doesn't say 30.
- If unblinded takes the drug out of the freezer and holds it in their hand (the vial) while filling out paperwork, etc. it will likely be thawed around 15 minutes and that shaves considerable amount of time off our pt wait time.
- I sent an email to Arturo with my thoughts/suggestions on the approximate language and I'm awaiting a written response from him before sending direction to the sites.

- Find Olivia's email and get a plan for VRG, send to Kristi/Olivia – Done
- Find Olivia's email and get a response back to Pfizer, cc Kristi/Olivia- Done
- CC-visits still pending from the 7th, and maybe earlier. That's just the last day I finally stopped checking.- I just checked CC (8/17/2020 3:57) and there are only two pts. Pending in CC from 8/3-8/14. One in Dallas and one in Arlington.
- Get Burt's help to get the laptops set up in FW- Done

Mercedes Livingston, CCRC
Chief Operating Officer

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Email: mercedeslivingston@ventaviaresearch.com

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From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Monday, August 17, 2020 8:57 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Action items for today.

Olivia Ray <image027.png>
Managing Member, Executive Director

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From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Monday, August 17, 2020 6:32 AM
To: Kristi Raney <kristiraney@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Kristi
Spoke with Christine last night
Will make up our 9 from last week today.
Then 20 to 24 set for tomorrow and then 20 to 24 set for Thursday. If we are shirt then weekly 40 by Thursday. The Saturday will be used to meet our weekly numbers.

Thanks for taking my call. And Houston will be on track after today.

Warm regards,

Email sent via cell phone

Lovica "Kandy" Downs
Regional Director/RMA, BBA, CCRC

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1307 8th Ave, Suite 202
Fort Worth. TX 76104
t: 817.269.5997
e: kdowns@ventaviaresearch.com

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www.platinum-research.net

-------- Original message --------
From: Kristi Raney <kristiraney@ventaviaresearch.com>
Date: 8/15/20 13:18 (GMT-06:00)
To: Kandy Downs <kdowns@ventaviaresearch.com>, Olivia Ray <oliviaray@ventaviaresearch.com>, Marnie Fisher <mfisher@ventaviaresearch.com>, Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>, Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: Re: Daily Status Calls Updates and Action Items

Kandy,

I was just looking in CC. It appears HOU only has 31 patients that randomized from last week. Why did they not hit their 40?

Next week, they have

M: 1
T: 21
W: 1
Th: 20
F: 0

I understand, Kandy, that Tran wants to see the patients at certain times he closes his practice, but this isn't working for us. First of all, they're not hitting their numbers. Second of all, when Pfizer increases the 40 doses, it will be hard for them to give them to HOU if they aren't hitting their 40 and they aren't doing it quickly.

If we need to consider utilizing our subI's (Garza or Kat) then that's what we have to do.

But I really needed my direction to be followed from the beginning. I understand that Tran had a different plan due to his patients and practice, but we can't allow that kind of stuff to impact a high-enrolling study. I know you brought this up on our call last week, but I didn't fully grasp the impact. In the future, if you need to detour off of my recruitment guidance, I need you to seek approval first before you agree or put anything into action. You brought the detour up really quickly on our call and it was already in place when you told me about it, so it was a little too late for me to say no (though I now realize I should have). The direction was to see the 40 patients within the first 2.5 days...so that when Pfizer did increase their cap, we'd be the first ones approved for additional druge (and I did clearly explain my strategy and the rationale behind it when I gave my direction). And now, Pfizer is planning to increase their drug and HOU didn't hit their 40 in the first week. Honestly, that's unacceptable. I need you to figure out how 9 patients will be randomized on Monday.

Recruitment is extremely strategic and it's not something that can have decisions made on the fly. We have had so many people give it a go...and the only other person who has been successful at it, is Mercedes (and obviously, she has no time for that right now). Katie Buchanan will be taking it over (training is starting this week) and the same guidance follows for her too. If she gives recruitment instruction, then no changes can be made unless approval is given by her (until she is trained, it's me).

Let me know if you have any questions.

Thanks,

Kristi

Kristi Raney
Managing Member, Executive Director

Ventavia Research Group

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817-394-1901 eFax

214-208-0390 Cell

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https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Friday, August 14, 2020 4:13 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

- Make sure HOU has same Complion plan in place as KEL and FW Houston is doing the same
    - Initial and dating any blanks as everything might have already been uploaded. Houston is QCing before uploading
    - Have all sites give an update by EOB Houston to upload about 10 more.
    - Tomorrow needs to be worked to get everything caught up Houston can't there is a building shutdown.
- Offer OT to anyone who can come in and get things caught up on Sat offered to all my sites.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

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1307 8th Ave Suite #202
Fort Worth, TX 76104
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eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

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<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Friday, August 14, 2020 9:30 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Olivia Ray <image016.png>
Managing Member, Executive Director

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t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>

www.ventaviaresearch.com

<image006.png>

<image026.png>

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Thursday, August 13, 2020 4:04 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

See in Red. From today.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

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<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Thursday, August 13, 2020 9:32 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Olivia Ray <image016.png>
Managing Member, Executive Director

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www.ventaviaresearch.com

<image006.png>

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From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Wednesday, August 12, 2020 4:59 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Hello- here is my daily task.
Pending only the CAPA, been working on Houston enrollment.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

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1307 8th Ave Suite #202
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Cell Number: 817-269-5997
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Email: kdowns@ventaviaresearch.com

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<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Wednesday, August 12, 2020 8:56 AM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Olivia Ray <image016.png>
Managing Member, Executive Director

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<image005.png>

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<image006.png>

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From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Tuesday, August 11, 2020 5:55 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

I did Kandy's in blue as well:

Marnie

- Cordy
  - Check-in on her, see if there is another unblinded that can replace her so she can get back to recruiting PENDING- need to figure out who we can use as a back-up (otherwise she's doing okay)
- Talk to Nika
  - Get Anne on the phones today, along with Alaina (do not pull them off the phones) DONE
  - Check on drug (arrived today)
  - Make sure they are knocking out new drug in 2.5 days (16/16/8) DONE
  - Make sure Katie is in Grapevine on Fri afternoon, so get help from someone else if needed DONE
  - Look at schedule ad drug, day by day and confirm if you need the additional help. If not, then please don't pull them (Alma, Becca, Kati D, etc.) DONE
  - Go over ediary issue/falsifying data, etc. DONE
- Talk to Becca
  - Help create the schedule for KEL COVID PENDING- I'LL CALL HER ON WAY HOME
- Talk to Dana
  - Go over Mer's email re: COVID scheduling DONE ON 8/10/20
  - Look at schedule ad drug, day by day and confirm if you need the additional help. If not, then please don't pull them DONE- discussed with Dana
  - Go over ediary issue/falsifying data, etc. DONE- Thea also verbally counseled for changing data and not noting late entry
- Chrystal
  - Tell her to change the visit time to 2 to 2.5 hours DONE on 8/10/20
  - She needs to train recruiters to start capturing race in CC DONE
- Talk to JV
  - First round of interviews, give her specific questions to weed out, forward her any contenders from Indeed PENDING- will try to call on way home
- Talk to your sites about capturing race in CC when a patient comes in PENDING- should we update the source documents?

Kandy

- Nikki-make sure unblinded for COVID (to free up Jailyn to see maternal pts), blinded for all maternal/pedi, eventual training on Medical Records DONE- I just talked to her myself and Kandy talked to Dana.
- Talk to Nadia (with Marnie)-can we get Nadia switched to onboarding/admin duties/take tasks over from Katie Buchanan for the next couple of months until Dana can take it back over. If she is, then please facilitate the process between KB and NM and the FW site to get this started. DONE- Kandy and I talked to Nadia together about everything (Linda issue, job function, etc.) She is eager to learn anything and everything, but is not sure she has time right now with all other duties. Kandy is trying to call Olivia to discuss an idea of Jazmine taking this on.
- Talk to Christine- DONE

- About the Complion upload station- new admin, Maria
- Go over ediary issue/falsifying data, etc. DONE

- Talk to your sites about capturing race in CC when a patient comes in PENDING

Regards,
Marnie

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Tuesday, August 11, 2020 9:10 AM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

See attached.

Olivia Ray <image016.png>
Managing Member, Executive Director

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<image006.png>

<image025.png>

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Tuesday, August 11, 2020 7:41 AM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

I missed this, Olivia, but I'll do this moving forward, thanks.

Marnie:

- Get resume over from Kati Dykes-possible CRC asst (DONE- Katie sent to Mercedes yesterday)
- Call Nika/Katie:
  - Anne needs to focus on scanning into Complion as much as possible this morning DONE- but tasks changed. Katie had Anne catching up the uploading of consents into eConsent and reviewing diaries. I took on scanning, but didn't get anywhere- still pending getting access to study in Complion. Kate apologized for the delay, she will get it done this morning.
  - Need to start scheduling starting Tues afternoon for new covid pts DONE
- Call FW:
  - Get a game plan in place to get Complion caught up in EOB today CALL DONE- but the task is PENDING
  - Move patients within their window to fit more COVID pts CALL DONE- but the task is PENDING. FW prefers to schedule as initially planned since appointments have already been made, for example, on Friday. However, FW confirms to schedule based on Mercedes new plan starting next week.
  - Let Dana know Mer needs to know when they have a pedi blood draw due to so many deviations, so she can go up and draw DONE- by Mercedes
- Call Jennifer Valo that she needs to be in FW the rest of the week DONE- will be in FW Wed and Friday and working on coverage for kids so she can be there Thursday
- Call Chrystal and:
  - Direct John to call for KEL DONE
  - Cordy cannot be responsible for KEL recruitment right now ACKNOWLEDGED- all parties know
  - Tell her OT is approved for nights and weekends so we can get spots filled WILL DO NOW
  - Let her know Shannon (anyone else), must call AND schedule DONE
  - If newbies have questions, put them on hold and ask a seasoned employee, bc everyone needs to be trained and, on the phones, as soon as they can DONE

Regards,
Marnie

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Monday, August 10, 2020 10:16 AM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>

Subject: RE: Daily Status Calls Updates and Action Items
Importance: High

Let's add another layer to this so we can make sure we are all staying on top of our lists:

- Set an alarm on your phone for 4pm
- Copy and paste your action items in an email reply back to this chain and state status (DONE or Pending-update as to why)

Example (and this is actually mine for today):

- Hiring-Indeed Ads-Tweak to add the following
  - HOU-CRC, FW-CRC, KEL-2 CRC, 3-5 years' experience-DONE

This is to create a new habit of double-checking if you complete your items by EOB. If not, then you are learning to pull your resources to help get it done before the next morning's call.

Thanks,

Olivia Ray 
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

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From: Olivia Ray
Sent: Monday, August 10, 2020 9:00 AM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>
Subject: Daily Status Calls Updates and Action Items

Olivia Ray 
Managing Member, Executive Director

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<Daily Status Updates 9.16.2020.docx>

Ex. 22

Brook Jackson

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Wednesday, September 9, 2020 1:31 PM
To: Brook Jackson
Subject: FW: Current Actions Items/Needing help

FYI

Regards,
Marnie

From: Kristi Raney <kristiraney@ventaviaresearch.com>
Sent: Tuesday, September 8, 2020 3:25 PM
To: Jailyn Reyes <jailynreyes@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Dana Duvak <danaduvak@ventaviaresearch.com>; Jen Vasilio <jvasilio@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: Re: Current Actions Items/Needing help

Jailyn,

Thanks for making sure you reach out for help when you feel like you aren't able to get to everything.

Have you had a chance to review this with Jen yet? If not, I'd like for you to review this with her and then the two of you come up with a gameplan. If you have arleady reviewed this with Jen, then I'd like for Jen to reach out to Marnie and let her know what has been put into place to help you...and where the site still needs to help you (and pull in the leadership team).

Again, thank you for letting us know you need help!! We are here for you and we will get you to a place where you feel like you can tackle your day.

Thanks, Jailyn!

Kristi Raney
Managing Member, Executive Director

Ventavia Research Group

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Fort Worth, TX 76104

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817-394-1901 eFax

214-208-0390 Cell

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From: Jailyn Reyes <jailynreyes@ventaviaresearch.com>
Sent: Tuesday, September 8, 2020 3:14 PM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Dana Duvak <danaduvak@ventaviaresearch.com>; Jen Vasilio <jvasilio@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: Current Actions Items/Needing help

Hello all,

I have been trying to work on all my action items by myself since we are all extremely busy, however it has been very difficult to get all my actions items completed in a timely manner. I am needing help to take some items off my plate if possible. Below, I am providing some of my action items.

With just the unblinded C4591001 and maternal C3671008, that takes all my time here at the office putting me behind on my other studies.

Unblinded C4591001- Vaccinations, Daily preparation sheets, drug confirmation sheets, and accountability logs to upload and file into Complion along with bi-weekly remote monitoring follow up visits. This takes most of the day while Nadia is doing most of the vaccines. Most of the time I do have to step in and help her with randomizing and vaccinating. I currently have over 120 documents that need to be filed but only the unblinded can do that.

C3671008-I currently have a patient in labor at 36 weeks and 5 days, working on AESI. Screening and follow up visits for the rest of the week, action items from remote monitoring visit conducted last week. I also have eDiaries to check and Bi-weekly phone calls.

AL29A- Close out visit action items that I have not been able to complete. The close out visit was conducted on 21AUG2020.

Estetra/Hot-Flash-patient coming in on 9/14/2020.

B1971057-Actions items including EDC queries.

Regards,

Jailyn Reyes
Clinical Research Coordinator & Certified
Medical Assistant

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Phone Number: (817) 348-0228
Fax Number: (817) 394-1901
Email: jailynreyes@ventaviaresearch.com

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Ex. 23

Rebecca Gibson

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Tuesday, September 22, 2020 8:21 PM
To: Jen Vasilio; Olivia Ray; Kristi Raney; Jailyn Reyes; Marnie Fisher; Brook Jackson
Subject: RE: Current Action Items/Needing help

Great updates, Jen.

As a reminder, you do have two more coordinators joining your team in the next two weeks so hopefully, both staff can be added to all current studies and help lighten everyone's job!

We know you all are very busy right now. I appreciate you, Jailyn reaching out and waving your white flag and you, Jennifer jumping in to help her out!

I'm seeing the FW team coming together and I'm so excited for you all!

Regards,

Mercedes

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
1307 8th Avenue, Suite 202
Ft. Worth, Tx 76104
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Cell: 817-845-3824
Fax Number: 817-394-1901
Email: mercedeslivingston@ventaviaresearch.com

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From: Jen Vasilio <jvasilio@ventaviaresearch.com>
Sent: Tuesday, September 22, 2020 5:18 PM

To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Jailyn Reyes <jailynreyes@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>
Subject: Re: Current Action Items/Needing help

Hi Ladies-

I apologize for the delay in closing the email loop on Jailyn's email, but please be assured that I have been in constant communication with Jailyn and working through all of the pending items she has listed below, since 09SEP2020 through today.

Below I have listed some of the items that are now implemented, to help lighten Jailyn's load.

Nadia is now doing all the vaccines for the COVID trial, to eliminate this from Jailyn's plate, occasionally if Nadia is behind or not in office, then Jailyn will jump in to vaccinate.

We are now utilizing the back-up CRC for the maternal trials, Linda.
Linda has been completing some of the maternal visits, when Jailyn has a monitor visit, or there are multiple maternal visits, etc.

Linda has also been helping with EDC queries, I have asked Jailyn and Linda to work to together to keep these up to date.
Linda has also offered to share "oncall" responsibilities for maternal trials with Jailyn.

Erin, is also a backup for the maternal trials and is completing training with Jailyn on Lab processing, and other trial procedures.
Erin has also offered to share "oncall" responsibilities for maternal trials with Jailyn.

Now that Nadia has moved to the fulltime research assistant position, this has also been a great help.
Nadia is also listed on the DOA and can help with Trial manager and EDC for the maternal trials.

Thank you, for bringing this to my attention.

Jen Vasilio

Site Operations Manager

Ventavia Research Group
1307 8th Ave., #202
Fort Worth, TX 76104
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Office: (817)348-0228
jvasilio@ventaviaresearch.com

From: Jailyn Reyes <jailynreyes@ventaviaresearch.com>
Sent: Tuesday, September 8, 2020 3:14 PM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Dana Duvak <danaduvak@ventaviaresearch.com>; Jen Vasilio <jvasilio@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: Current Actions Items/Needing help

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AL29A- Close out visit action items that I have not been able to complete. The close out visit was conducted on 21AUG2020.

Estetra/Hot-Flash-patient coming in on 9/14/2020.

B1971057-Actions items including EDC queries.

Regards,

Jailyn Reyes
Clinical Research Coordinator & Certified
Medical Assistant

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Email: jailynreyes@ventaviaresearch.com

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Ex. 24

- ICF errors- Training- William
  - Signatures from one page to the next not matching up
  - Brook- incorrect dates used by the patients
  - Printer copies not being clear (sloppy, cutting off footers, etc)
  - Inconsistency in where the ICF documentation process form is kept
    - Screening should be embedded in the screening source
    - Re-consent ICF documentation will be kept on top of the revised ICF
  - Update ICF documentation form with a comment section to document any questions that the patients have for the ICF process- this is a place where they can document questions and answers that the subject had during the visit – Mer will take this
    - Update ICF documentation page to have blanks for the CRC initials instead of checkboxes
    - Add a statement asking if the ICF was checked for Quality Assurance (signature verification, date formats, consistent initials, etc) by the consenter
    - CRC don't know to be documenting questions/comments/conversations had about the ICF in the progress notes
  - Proper ICF QCing process
    - CAPA needed at all three sites for the top three ICF errors- **RD** to create the CAPA for consent for all three sites and submit to Mercedes for review by **COB 9/23/2020**
- Randomization confirmations staying in the charts
  - Randomization confirmations needs to come out of the charts
  - Drug assignments need to come out (if they were in there)
    - CAPA needed that the source stated to file the IMPALA randomization and drug assignment confirmation page was required to be filed in the chart. Drug assignments were never filed in the charts however the randomization documents were but upon guidance from the sponsor, they were removed. William due to team by **COB 9/23/2020**
    - CAPA also addressing overall source issues and good documentation-William due to team by **COB 9/23/2020**
- Write overs- Training William
  - Correctly making changes
  - Patients making changes correctly on Consents-
- Source version- Training- William
  - Using the wrong version of source
    - Source control is an opportunity for growth at all sites
    - PM creates source and sends to leads for reviews
    - Sends to Regulatory to finalize and be the "keeper" of all the versions
    - Regulatory will update the headers/footers with site information for each participating site
    - Regulatory will send the approved final copy of source/revised source to sites through Complion with explanation of update and request signatures for training

        - Regulatory sends approved/revised source to sites, they will also call sites to notify revised source is being sent
        - Sites will print source from Complion vs SharePoint
        - Regulatory will need to upload source version to SharePoint
- Risk factors being checked but not going into medical history- Training – William
    - Consistency sake, primary endpoints, all these need to be compared
    - Ensure those that need to go in MedHx are listed there
    - CAPA will fall under good documentation practices
- IUD in WOCBP page but not in CM- Training- William
    - Should insertion also be placed in MedHx- preventative vs. procedure
    - Tubal ligation- documenting bilateral, etc
- Not being placed in IMPALA until later in the visit (instead of after consent) – William training
    - Waiting on response from Arturo on this
- Blanks in the charts (unscheduled visit with physical page not completed)- William Training
- Patients location during 30 minute waiting period- Training Mer
    - Be in the waiting area where the receptionist can see the patients
    - If in the hallway, a staff member needs to be in the hallway with a work station
    - Patients need to be brought back into a room for 30-minute post observation period
- CM indication not matching med hx term- Training William
    - Back muscle spasms and degenerative disk disease listed in MedHX
    - CM listed as taken for back pain but no back pain in MedHx
    - Procedures listed in MedHx but not indication for procedure
    - MedHx start dates and CM start dates not lining up (CM starting before MedHx condition)
- Medical History page- revised to take out question asking if the subject has past or present medical or surgical history. - Kate
    - Add yes/no after the bolded question
    - Taking out Yes/No for each system
- Progress noting issues- Training William
    - Pt used MLR (pt info sheet) vs MHR (DL) no progress note as to why CRC used license vs what pt put on MedHX list
    - Devices- Trianing
    - Pt initially requested a device and one was given
    - At next visit, requested to use the app and we didn't document if the device was collected from the subject
- Schedule of events- Training Mer
    - Remove from charts all together
    - PMs created laminated "kit" with rings for all the pages that are needed for patient education.
    - One will go back with patients at each visit
    - This can be reviewed during the pre-study training
    - Create NTF that statement in the source "Has the protocol Schedule of Activities been reviewed to ensure all visit procedures have been completed" is signed off by the CRC and is being reviewed on a master copy – MER

- E-diary email about AEs- what is the question here? - Training William
    - Symptoms noted in the e-diary regardless of if they are ongoing after Day 7 or not are not to be reported as AEs
    - Patients outside of the reactogenicity subset if they have symptoms after vaccine should be reporting in the illness visit e-diary page
    - Protocol pages 92-95
- E-diary- Training William
    - Visit 2 and Visit 3- question regarding e-diary issues
    - Source to be updated asking if there are problems with the e-diary
        - Separate question if the subject missed any days during the e-diary reporting period
    - E-diaries are to be printed on Day 8 (after 7 day period) and signed by the PI as soon as possible (within 2-3 days from printing)
    - Patient ID/initials and Study number aren't on the e-diary print-out-
- Source document of WOCBP- Training MER- Video
    - Signature statement should only be signed if the subject's methods of contraception could change while in the study
    - WOCBP should be updated with an NA box for signature if post-menopausal/hysterectomy
    - NTF- clarifying what the statement is meant to say and what the CRC and Investigator are signing on - MER
    - Source to be updated clarifying statement in WOCBP template and study source. MER

Resolution- create a check list for what needs to be completed in each chart and export a list of patients for items to be completed/taken out of each chart.

Get all charts completed by **COB on Friday**

Ex. 25

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001 **PI: Mark Koch, MD** **Site: 1128**
Laboratory: Covance **Sampling Type: Blood**

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1066	V3	24sep2020 922	32	955	24sep2020 1011	24sep2020 1016	24sep2020 MQ
1128 1036	V3	24sep2020 1013	41	1054	24sep2020 1117	24sep2020 1125	24sep2020 MQ
1128 1064	V3	24sep2020 1155	40	1135	24sep2020 1214	24sep2020 1216	24sep2020 MQ
1128 1072	V3	24sep2020 1145	31	1216	24sep2020 1241	24sep2020 1545 MQ	24sep2020 MQ
1128 1070	V3	24sep2020 1430	35	1505	24sep2020 1524	24sep2020 1536	24sep2020 MQ
1128 1067	V3	24sep2020 1454	31	1525	24sep2020 1542	24sep2020 1546 Hott 24sep2020	24sep2020 MQ
1128 1057	V3	24sep2020 1511	31	1542	24sep2020 1606	24sep2020 1611 1639 MQ	24sep2020 MQ
1128 1015	V3	24sep2020 1535	35	1610	24sep2020 1628	24sep2020 1639	24sep2020 MQ
1128 1013	V3	24sep2020 11:01	309	1610	24sep2020 1629	24sep2020 1642	24sep2020 MQ

JSN04468

120

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001 **PI: Mark Koch, MD** **Site: 1128**
Laboratory: Covance **Sampling Type: Blood**

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze Immediately)	CRC Initials/Date
1128 1042	V3	23sept 2020 1101	34	1133	23sep2020 1151	23sep2020 1156	23Sep2020 MR
1128 1035	V3	23sep2020 1112	02	1150	23Sep2020 1206	23sep2020 1208	23Sep2020 MR
1128 1308	V1	23Sep2020 1243	56	1314	23sep2020 1333	23Sep2020 1337	23 Sep2020 MR
1128 ~~7304~~ 1036 MR 23 Sep2020	V3	23sep2020 1255	69	1314	23Sep2020 1410	23Sep2020 1416	23Sep2020 MR
1128 1054	V3	23Sep2020 1416	39	1455	23Sep2020 1510	23 sep2020 1521	23 sep2020 MR
1128 1384	V1	23sep2020 MR 1427	39	~~1528~~ 1528 23MR Sep2020	23Sep2020 1530	23Sep2020 1533	23Sep2020 MR
1128 1039	V3	23Sep2020 MR 43 ~~1534~~	58	1616	23Sep2020 1632	23 Sep2020 1637	23Sep 2020 MR
1128 1030	V3	24Sep2020 0846	66	0920	24Sep2020 936	24 Sep2020 944	24Sep2020 MR
1128 1040	V3	24 Sep2020 856	76	0920	24Sep2020 952	24 Sep 2020 957	24 Sep2020 MR

JSN04469

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001 **PI: Mark Koch, MD** **Site: 1128**
Laboratory: Covance **Sampling Type: Blood**

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1022	V3	21 Sep 2020 1013	32	1045	21 Sep 2020 1702	21 Sep 2020 1710	21 Sep 2020 MR
1128 1008	V3	22 Sep 2020 944	60	1016	22 Sep 2020 1033	22 Sep 2020 1039	22 Sep 2020 MR
1128 1007	V3	22 Sep 2020 941	57	1016	22 Sep 2020 1038	22 Sep 2020 1042	22 Sep 2020 MR
1128 1026	V3	22 Sep 2020 1014	58	1044	22 Sep 2020 1102	22 Sep 2020 1109	22 Sep 2020 MR
1128 1031	V3	22 Sep 2020 1212	32	1244	22 Sep 2020 1311	22 Sep 2020 1320	22 Sep 2020 MR
1128 1047	V3	22 Sep 2020 1408	48	1440	1489 22 Sep 2020	22 Sep 2020 1503	22 Sep 2020 MR
1128 1024	V3	22 Sep 2020 1530	38	1608	22 Sep 2020 1626	22 Sep 2020 1634	22 Sep 2020 MR
1128 1032	V3	23 Sep 2020 900	33	933	23 Sep 2020 950	23 Sep 2020 955	23 Sep 2020 MR
1128 1033	V3	23 Sep 2020 932	41	1009	1025 23 Sep 2020	23 Sep 2020 1030	23 Sep 2020 MR

JSN04470

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1016	V3	18 sept 2020 1612	30	1642	18 sept 2020 1712	18 sept 2020 1717	18 sept 2020 MR
1128 1318	V1	18 sept 2020 1619	38	1653	18 sept 2020 1712	18 sept 2020 1717	18 sept 2020 MR
1128 1029	V3	18 sept 2020 1650	32	1720 ~~1654~~ 18 sept 2020 MR	18 sept 2020 1738	18 sept 2020 1740	18 sept 2020 MR
1128 1043	V3	21 sept 2020 1010	42	1052	1722 21 sep 2020 MR	21 sep 2020 1134	21 sep 2020 MR
1128 1041	V3	21 sept 2020 1010	42	1052	21 sep 2020 1122	21 sept 2020 1134	21 sep 2020 MR
1128 1040	V3	21 sep 2020 1015	45	1100	21 sept 2020 1144	21 sept 2020 1151	21 sep 2020 MR
1128 1037	V3	21 sep 2020 1215	60 did not clot	~~1434~~	21 sep 2020 1440	21 sep 2020 1444	21 sep 2020 MR
~~1128 18~~ ERROR MR 21 sep 2020							MR
~~1128~~ ERROR 21 sep 2020							MR

JSN04471

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001 **PI: Mark Koch, MD** **Site: 1128**
Laboratory: Covance **Sampling Type: Blood**

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1006	V3	18sept2020 1045	30	1115	18sept2020 1123	18sept2020 1130	18sept2020 MQ
1128 1379	V1	18sept2020 1059	02	MQ 18sept2020 HO 1125	18sept2020 1133	18sept2020 1140	18sept2020 MQ
1128 1025	V3	18sept2020 1059	02	1125	18sept2020 1134	18sept2020 1143	18sept2020 MQ
1128 1004	V3	18sept2020 9:09	49	940	18sept2020 948	18sept2020 1023	18sept2020 MQ
1128 1002	V3	18sept2020 1240	30	13:11	18sept2020 13:34	18sept2020 13:36	18sept2020 MQ
1128 1382	V1	18sept2020 1335	38	1359	18sept2020 1426	18sept2020 1429	18sept2020 MQ
1128 1383	V1	18sept2020 1347	36	1417	18sept2020 1492	18sept2020 1444	18sept2020 MQ
~~1128 1022~~ 1128 1020 MQ 18sept2020	V3	18sept2020 1422	42	1504	18sept2020 1522	18sept2020 1523	18sept2020 MQ
1128 1021 MQ 18sept2020	V3	18sept2020 1538	38	1600	18sept2020	18sept2020	18sept2020 MQ

JSN04472

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze Immediately)	CRC Initials/Date
11281262	V1	17SEP2020 0957	32	~~1029~~ 1029	17SEP2020 1043	17SEP2020 1050	~~AB~~ 17SEP2020
11281027	V3	17SEP2020 1007	34	1041	17SEP2020 1058	17SEP2020 1103	~~AB~~ 17SEP2020
11281376	V1	17SEP2020 1010	31	1041	17SEP2020 1059	17SEP2020 1103	~~AB~~ 17SEP2020
11281018	V3	17SEP2020 1043	41	1125	17SEP2020 11:45	17SEP2020 11:50	17 Sep 2020 JD
11281377	V1	17SEP2020 1137	68	1245	17SEP2020 1304	17SEP2020 1307	17SEP2020 ~~LBR~~
11281378	V1	17SEP2020 1157	48	1245	17SEP2020 1305	17SEP2020 1307	17SEP2020 ~~LBR~~
11281380	V1	17SEP2020 1425	30	1455	17SEP2020 1323	17SEP2020 1325	17SEP2020 ~~LBR~~
11281381	V1	17SEP2020 1453	32	1525	17SEP2020 1544	17SEP2020 1549	~~LBR~~ 17SEP2020
11281017	V3	18 Sept 2020 1030	32	1102	18Sept2020 1130	18 Sept 2020 1134	18Sept2020 ~~ne~~

JSN04473

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
11281001	V3	16 SEP 2020 1145	80	~~1407~~ 1305 9-16-2020	16 SEP 2020 1330	16 SEP 2020 1354	16 SEP 2020
11281371	V1	16 SEP 2020 1205	60	~~1407~~ 1305 9-16-2020	16 SEP 2020 1330	16 SEP 2020 1354	16 SEP 2020
11281370	V1	16 SEP 2020 1324	37	1401	16 SEP 2020 1435	16 SEP 2020 1441	16 SEP 2020
11281009	V3	16 SEP 2020 1325	36	1401	16 SEP 2020 1438	16 SEP 2020 1441	16 SEP 2020
11281372	V1	16 SEP 2020 1323	38	1401	16 SEP 2020 1438	16 SEP 2020 1441	16 SEP 2020
11281373	V1	16 SEP 2020 1431	31	1502	16 SEP 2020 1534	16 SEP 2020 1535	16 SEP 2020
11281374	V1	16 SEP 2020 1624	32	1656	16 SEP 2020 1713	16 SEP 2020 1715	16 SEP 2020
11281375	V1	16 SEP 2020 1645	31	1716	16 SEP 2020 1750	16 SEP 2020 1758	16 SEP 2020
11281011	V3	17 SEP 2020 0854	—		17 SEP 2020 1015	17 SEP 2020 1022	16 SEP 2020

JSN04474

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001 **PI: Mark Koch, MD** **Site: 1128**
Laboratory: Covance **Sampling Type: Blood**

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze Immediately)	CRC Initials/Date
n/a							
1128 1363	V1	15sept2020 1403	30	15 sept2020 1453	15sept2020 1500	15sept2020 1612	15sept2020 MQ
1128 1362	V1	1217	40	15 sept2020 1300	15 Sept 2020 1322	15sept2020 1345	15Sept2020 MQ
1128 1364	V1	1426	42	15 sept2020 1458	15sept2020 1509	15 sept2020 1530	15Sept2020 MQ
1128 1365	V1	1428	40	15 sept2020 1458	15sept2020 1512	15 sept2020 1538	15 Sept 2020 MQ
11281366	V1	1632	63	1735	1740	17:43	09/15/2020
1128 1368	V1	955	35	16 Sept 2020 1030	16 Sept 2020 1042	16 Sept 2020 1046	16 Sept 2020 MQ
1128 1367	V1	1007	30	16 Sept 2020 1033	16 Sept 2020 1050	16 Sept 2020 1053	16 Sept 2020 MQ
1128 1010	V3	1108	—		16SEP2020 1300 KB	16SEP2020 1340 KB	16SEP2020 KB

JSN04475

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001 **PI: Mark Koch, MD** **Site: 1128**
Laboratory: Covance **Sampling Type: Blood**

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
11281353	V1	14sept2020 1200	30	1244	14sept2020 1300	14sept2020 1304	14sept2020 MR
11281005	V3	14sept2020 1448	38	1549	14sept2020 1556	14sept2020 1600	14sept2020 MR
11281354	V1	14sept2020 1518	31	1549	14sept2020 1620	14sept2020 1622	14sept2020 MR
11281355	V1	14sept2020 1519	32	1550	14sept2020 1620	14sept2020 1622	14sept2020 MR
11281356	V1	14sept2020 1605	30	1640	14sept2020 1645	14sept2020 1648	14sept2020 MR
11281358	V1	15sept2020 923	45	1012	15sept2020 1028	15sept2020 1030	15Sept2020 MR
11281357	V1	15sept2020 924	45	1012	15sept2020 1028	15sept2020 1031	15Sept2020 MR
11281359	V1	15sept2020 1014	30	1050	15sept2020 1058	15Sept2020 1100	15Sept2020 MR
11281360	V1	15sept2020 1031	35	1103	15sept2020 1127	15Sept2020 1129	15Sept2020 MR

JSN04476

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001 **PI: Mark Koch, MD** **Site: 1128**
Laboratory: Covance **Sampling Type: Blood**

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128/344	V1	12sept2020 1126	36	1200	12sept2020 1216	12sept2020 1220	12sept2020 MG
1128/347	V1	12sept2020 1125	35	1159	12sept2020 1216	12sept2020 1218	12sept2020 MG
1128/346	V1	12sept2020 1203	43	1240	12sept2020 1252	12sept2020 1254	12sept2020 MG
1128/348	V1	12sept2020 1344	30	1416	12sept2020 1443	12sept2020 1503	12sept2020 MG
1128/350	V1	12sept2020 1403	38	1441	12sept2020 1501	12sept 2020 1508	12sept2020 MG
1128/349	V1	12sept2020 1336	30	1408	12sept2020 1443	12sept2020 1503	12sept2020 MG
1128/351	V1	12sept2020 1441	62	1548	12sept2020 1601	12sept2020 1610	12sept2020 MG
1128/352	V1	12sept2020 1547	36	1634			
					↑ done 14 Sept 2020 By April		

JSN04477

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
11281331	V1	11Sept2020 1144	38	1436	11Sept2020 1440	11Sept2020 1450	11Sept2020 MR
11281333	V1	11Sept2020 1302	38	1436	11Sept2020 1442	11Sept2020 1453	11Sept2020 MR
11281336	V1	11Sept2020 1400	30	1430	11Sept2020 1500	11Sept2020 1502	11Sept2020 MR
11281335	V1	11Sept2020 1414	39	1453	11Sept2020 1502	11Sept2020 1530	11Sept2020 MR
11281339	V1	11Sept2020 1532	32	1602	11Sept2020 1625	11Sept2020 1630	11Sept2020 MR
11281341	V1	11Sept2020 1602	31	1635	11Sept2020 1700	11Sept2020 1705	11Sept2020 MR
11281342	V1	11Sept2020/17:25	45	18:10	11Sept2020 1828	11Sept2020 1829	11Sept2020 MR
11281345	V1	11Sept2020 959	30	1032	12Sept2020 1055	12Sept2020 1056	12Sept2020 MR
11281343	V1	11Sept2020 1003	30	1034	12Sept2020 1054	12Sept2020 1056	12Sept2020 MR

JSN0478

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001 **PI: Mark Koch, MD** **Site: 1128**
Laboratory: Covance **Sampling Type: Blood**

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128324	V1	10 Sept 2020 mg 1505	35 30 mg 10 sept 20	1540	10 Sept 2020 1542	10 Sept 2020 1548	10 Sept 2020 mg Per Sequin
1128323	V1	10 Sept 2020 mg 1540	30	1614	10 Sept 2020 1645	10 Sept 2020 1650	10 Sept 2020 mg
1128326	V1	10 Sept 2020 mg 1621	30	1703	10 Sept 2020 1715	10 Sept 2020 1726	10 Sept 2020 mg
1128327	V1	10 Sept 2020 1705	30	1738	10 Sept 2020 1739	10 Sept 2020 1742	10 Sept 2020 mg
1128328	V1	LBL 9-10-2020 1758	32	1830 LBL 9-10-20	10 SEP 2020 1848	10 SEP 2020 1850	LBL 10 SEP 2020
1128 1329	V1	10 SEP 2020 1901	36	1937	10 SEP 2020 2003	10 SEP 2020 2006	TJS 10 SEP 2020
1128317	V1	11 Sept 2020 9:19	32	10:08	11 Sept 2020 1025	11 Sept 2020 1027	11 Sept 2020 mg
1128330	V1	11 Sept 2020 1119	36	1155	11 Sept 2020 1205	11 Sept 2020 1210	11 Sept 2020 mg
1128332	V1	11 Sept 2020 1122	36	1155	11 Sept 2020 1209	11 Sept 2020 1215	11 Sept 2020 mg

JSN04479

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001 **PI:** Mark Koch, MD **Site:** 1128
Laboratory: Covance **Sampling Type:** Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1312	V1	1301	30	1400	9Sept2020 1405	9Sept2020 1408	9Sept2020 MQ
1128 1313	V1	1514	30	1540	9Sept2020 1543	9Sept2020 1549	9Sept2020 MQ
1128 1315	V1	1544	30	1615	9Sept2020 1622	9Sept2020 1640	9Sept2020 MQ
1128 1314	V1	1558	30	1615	9Sept2020 1642	9Sept2020 1656	9Sept2020 MQ
1128 1316	V1	1601	30	1648	9Sept2020 1651	9Sept2020 1700	9Sept2020 MQ
18Sept2020 MQ 1128 1319	V1	1740	30	1820	9Sept2020 1836	09Sept2020 1834	9Sept2020 MQ
1128 1320	V1	11:09	30	1147	10Sept2020 1215	10Sept2020 1230	10Sept2020 MQ
1128 1321	V1	1315	30	1147	10Sept2020 1447	10Sept2020 1450	10Sept2020 MQ
1128 1322	V1	1354	30	1447	10Sept2020 1449	10Sept2020 1449	10Sept2020 MQ

JSN0480

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1302	V1	1548	30	1615	8sept2020 1845	8sept2020 1900	8 sept2020 MR
1128 1299	V1	1504	30	1620	8sept2020 1845	8sept2020 1900	8sept2020 MR
1128 1305	V1	1548	30	1850	8sept2020 1858	8sept2020 1900	8 sept2020 MR
1128 1303	V1	1649	30	1840	8sept2020 1900	8sept2020 1920	8 sept2020 MR
1128 1304	V1	1658	30	1845	8sept2020 1900	8sept2020 1920	8sept2020 MR
1128 1307	V1	9sept2020 1045	30	1207	9sept2020 1228	9sept2020 1229	9sept2020 MR
1128 1306	V1	9sept2020 1040	30	1207	9sept2020 1228	9sept2020 1229	9sept2020 MR
1128 1309	V1	9sept2020 1209	30	1245	9sept2020 1349	9sept2020 1340	9 sept2020 MR
1128 1311	V1	9sept2020 1243	30	1340	9sept2020 1342	9 sept2020 1355	9Sept2020 MR

JSN04481

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1292	V1	04 Sep 2020 17:16	30 min	17:46	04/Sep/2020 18:19	04/Sep/2020 18:20	09/04/2020
1128 1293	V1	08 Sept 2020 1036	30	11:08	08/Sept/2020 1132	08 Sept 2020 1135	mg 8 Sept 2020
1128 1294	V1	08 Sept 2020 1035	50	11:15	08/Sept 2020 1134	08 Sept 2020 1135	mg 8 Sept 2020
1128 1295	V1	08 Sept 2020 1049	30	11:40	8 Sept 2020 1152 mg 8/Sept/2020 ~~1152~~	08 Sept 2020 1155 mg 8/Sept/2020 ~~1155~~	mg 8/Sept/2020
1128 1296	V1	08 Sept 2020 1132	30	1200	8 Sept 2020 1205	8 Sept 2020 1207	8 Sept 2020 mg
1128 1297	V1	08 Sept 2020 1220	30	1303	8 Sept 2020 1305	8 Sept 2020 1310	8 Sept 2020 mg
1128 1298	V1	8 Sept 2020	30	1610	8 Sept 2020 1620	8 Sept 2020 1622	8 Sept 2020 mg
1128 1300	V1	08 Sept 2020 1505	30	1630	8 Sept 2020 1638	8 Sept 2020 1640	8 Sept 2020 mg
1128 1301	V1	08 Sept 2020 1451	30	16:00	8 Sept 2020 1620	8 Sept 2020 1622	8 Sept 2020 mg

JSN0482

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1281	V1	03 Sept 2020 1655	30	03 Sept 2020 1713	03 Sept 2020 1732	03 Sept 2020 1740	03 Sept 2020 MQ
1128 1283	V1	03 Sept 2020 1645	30	03 Sept 2020 1712	03 Sept 2020 1735	03 Sept 2020 1740	03 Sept 2020 MQ
1128 1282	V1	03 Sept 2020 1750	30	03 Sept 2020 1824	03 Sept 2020 1840	03 Sept 2020 1900	03 Sept 2020 MQ
1128 1284	V1	04 Sept 2020 1115	30	04 Sept 2020 1140	04 Sept 2020 1240	04 Sept 2020 1309	04 Sept 2020 MQ
1128 1285	V1	04 Sept 2020 1150	30	04 Sept 2020 1202	04 Sept 2020 1255	04 Sept 2020 1302	04 Sept 2020 MQ
1128 1286	V1	04 Sept 2020 1152	30	04 Sept 2020 1202	04 Sept 2020 1240	04 Sept 2020 1309	04 Sept 2020 MQ
1128 1288	V1	04 Sept 2020 1223	30	04 Sept 2020 1302	04 Sept 2020 1310	04 Sept 2020 1310	04 Sept 2020 MQ
1128 1289	V1	04 Sept 2020 1248	~~03 Sept 2020 30~~ 30	04 Sept 2020 1327	04 Sept 2020 1357	04 Sept 2020 1359	04 Sept 2020 MQ
1128 1291	V1	04 Sept 2020 14:40	30	04 Sept 2020 1515	04 Sept 2020 1530	04 Sept 2020 1531	04 Sept 2020 MQ

JSN0483

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001 **PI: Mark Koch, MD** **Site: 1128**
Laboratory: Covance **Sampling Type: Blood**

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128271	V1	02Sept 2020 1416	30	03Sept 2020 1530	02Sept 2020 1536	03 Sept 2020 1550	MG 03Sept 2020
1128273	V1	02Sept 2020 1558	30	1620	1624	03 Sept 2020 1630	MG 03Sept 2020
1128274	V1	03Sept 2020 1147	30	03 Sept 2020 1257	03 Sept 2020 1300	03 Sept 2020 1302	MG 03 Sept 2020
1128275	V1	03Sept 2020 1207	30	03 Sept 2020 1257	03 Sept 2020 1303	03 Sept 2020 1302	03 Sept 2020 MG
1128276	V1	03Sept 2020 1308	30	03Sept 2020 1340	03 Sept 2020 1340	03Sept 2020 1432	03 Sept 2020 MG
1128278	V1	03Sept 2020 1440	30	03Sept 2020 1520	03 Sept 2020 1530	03 Sept 2020 1549	03 Sept 2020 MG
1128277	V1	03Sept 2020 1524	30	03 Sept 2020 1537	03Sept 2020 1625	03Sept 2020 1625	03 Sept 2020 MG
1128279	V1	03 Sept 2020 1543	30	03 Sept 2020 1624	03 Sept 2020 1640	03 Sept 2020 1650	03Sept 2020 MG
1128280		03Sept 2020 1636	30	03Sept 2020 1700	03Sept 2020 1709	03 Sept 2020 1730	03 Sept 2020 MG

JSN0484

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1261	V1	01 Sept 2020 1919	01 Sept 2020 1921	30	01 Sept 2020 1950	01 Sept 2020 1956	01 Sept 2020 MQ
1128 1260	V1	01 Sept 2020 1900	01 Sept 2020 1920	30	01 Sept 2020 1950	01 Sept 2020 1956	01 Sept 2020 MQ
1128 1246	V1	02 Sept 2020 0855	30	02 Sept 2020 0930	02 Sept 2020 0949	01 Sept 2020 1000	02 Sept 2020 MQ
1128 1263	V1	02 Sept 2020	30	02 Sept 2020	02 Sept 2020	02 Sept 2020	02 Sept 2020 MQ
1128 1264	V1	02 Sept 2020 1043	30	02 Sept 2020 1122	02 Sept 2020 1146	02 Sept 2020 1148	02 Sept 2020 MQ
1128 1265	V1	02 Sept 2020 1050	30	02 Sept 2020 1146	02 Sept 2020 1200	02 Sept 2020 1202	02 Sept 2020 MQ
1128 1267 Arrio	V1	02 Sept 2020	30	02 Sept 2020	02 Sept 2020 1200	02 Sept 2020 1210	02 Sept 2020 MQ
1128 1269	V1	02 Sept 2020 1338	30	MQ 1428 02 Sept 2020 ~~1350~~	02 Sept 2020 1440	02 Sept 2020 1456	02 Sept 2020 MQ
1128 1268	V1	02 Sept 2020	30 MQ 01 Sept 2020	1350	02 Sept 2020 1352	02 Sept 2020 1352	02 Sept 2020 MQ

send 2mL 2mL 5mL 02 Sept 2020

JSN04485

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1248	V1	01 Sept 2020 1223	41	01 Sept 2020 1318	01 Sept 2020 1326	01 Sept 2020 1329	01 Sept 2020 MR
1128 1249	V1	01 Sept 2020 1249	36	01 Sept 2020 1330	01 Sept 2020 1335	01 Sept 2020 1340	01 Sept 2020 MR
1128 1250	V1	01 Sept 2020 1301	32	01 Sept 2020 1337	01 Sept 2020 1355	01 Sept 2020 1400	01 Sept 2020 MR
1128 1251	V1	01 Sept 2020 1430	30	01 Sept 2020 1501	01 Sept 2020 15:09	01 Sept 2020 15:16	01 Sept 2020 MR
1128 1252	V1	01 Sept 2020 1346	30	01 Sept 2020 1430	01 Sept 2020 1519	01 Sept 2020 1527	01 Sept 2020 MR
1128 1253	V1	01 Sept 2020 1529	30	01 Sept 2020 1605	01 Sept 2020 1628	01 Sept 2020 1720	01 Sept 2020 MR
1128 1256	V1	01 Sept 2020 1659	30	01 Sept 2020 1715	01 Sept 2020 1728	01 Sept 2020 1805	01 Sept 2020 MR
1128 1257	V1	01 Sept 2020	30	01 Sept 2020 1730	01 Sept 2020 1750	01 Sept 2020 1810	01 Sept 2020 MR
1128 1255	V1	01 Sept 2020 1718	30	01 Sept 2020 1746	01 Sept 2020 1748	01 Sept 2020 1753	01 Sept 2020 MR

JSN0486

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1237	V1	31 Aug 2020 1508	39	31 Aug 2020 1541	31 Aug 2020 1605	31 Aug 2020 16:16	MG 31 Aug 2020
1128 1239	V1	31 Aug 2020 1510	35	31 Aug 2020 1545	31 Aug 2020 1615	31 Aug 2020 1630	MG 31 Aug 2020
1128 1240	V1	31 Aug 2020 1014	30	31 Aug 2020 1637	31 Aug 2020 1653	31 Aug 2020 1700	MG 31 Aug 2020
1128 1241	V1	31 Aug 2020 1558	30	31 Aug 2020 1637	31 Aug 2020 1655	31 Aug 2020 1705	31 Aug 2020 MG
1128 1242	V1	31 Aug 2020 1029	46	31 Aug 2020 1717	31 Aug 2020 1742	31 Aug 2020 1758	31 Aug 2020 MG
1128 1243	V1	31 Aug 2020 1714	30	31 Aug 2020 1815	31 Aug 2020 1829	31 Aug 2020 1829	31 Aug 2020 MG
1128 1244	V1	01 Sept 2020 0940	30	01 Sept 2020 1030	01 Sept 2020 1039	01 Sept 2020 1040	01 Sept 2020 MG
1128 1245	V1	01 Sept 2020 1021	01 Sept 2020 MG 50 01	01 Sept 2020 1146	01 Sept 2020 1150	01 Sept 2020 1152	01 Sept 2020 MG
1128 1247	V1	01 Sept 2020	30	01 Sept 2020	01 Sept 2020 1145	01 Sept 2020 1150	01 Sept 2020 MG

JSN0487

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1230	V1	31 Aug 2020 1035	35	31 Aug 2020 11:10	31 Aug 2020 1158	31 Aug 2020 12:11	MR 31 Aug 2020
1128 1231	V1	31 Aug 2020 1049	30	31 Aug 2020 11:10	31 Aug 2020 1159	31 Aug 2020 12:21	MR 31 Aug 2020
1128 1229	V1	31 Aug 2020 1030	Mar 31 Aug 2020 30 42	31 Aug 2020 11:12	31 Aug 2020 1200	31 Aug 2020 1222	MR 31 Aug 2020
1128 1232	V1	31 Aug 2020 1141	30	31 Aug 2020 1233	31 Aug 2020 1245	31 Aug 2020 1246	MR 31 Aug 2020
1128 1233	V1	31 Aug 2020 1232	42	31 Aug 2020 1310	31 Aug 2020 1331	31 Aug 2020 1333	MR 31 Aug 2020
1128 1234	V1	31 Aug 2020 1315	36	1345 31 Aug 2020	1352 31 Aug 2020	1418 31 Aug 2020	MR 31 Aug 2020
1128 1236	V1	31 Aug 2020 1345	30	1405 31 Aug 2020	1430 31 Aug 2020	1438 31 Aug 2020	MR 31 Aug 2020
1128 1235	V1	31 Aug 2020 1434	30	1504 31 Aug 2020	1528 31 Aug 2020	1535 31 Aug 2020	MR 31 Aug 2020
1128 1238	V1	31 Aug 2020 1500	36	31 Aug 2020 1536	31 Aug 2020 1554	31 Aug 2020 1600	31 Aug 2020 MR

JSN0488

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
11281221	28 AUG 2020 V1	28 AUG 2020 1043	34	28 AUG 2020 1117	28 AUG 2020 1142	28 AUG 2020 1143	LBL 28 AUG 2020
11281220	28 AUG 2020	28 AUG 2020 1133	31	28 AUG 2020 1204	28 AUG 2020 1223	28 AUG 2020 1224	LBL 28 AUG 2020
11281222	28 AUG 2020	28 AUG 2020 1204	49	28 AUG 2020 1255	28 AUG 2020 1325	28 AUG 2020 1328	LBL 28 AUG 2020
11281223	28 AUG 2020	28 AUG 2020 1225	30	28 AUG 2020 1255	28 AUG 2020 1326	28 AUG 2020 1328	LBL 28 AUG 2020
11281224	28 AUG 2020	28 AUG 2020 1316	41	28 AUG 2020 1357	28 AUG 2020 1617	28 AUG 2020 1618	LBL 28 AUG 2020
11281225	28 AUG 2020	28 AUG 2020 1438	34	28 AUG 2020 1612	28 AUG 2020 1634	28 AUG 2020 1639	LBL 28 AUG 2020
11281226	28 AUG 2020	28 AUG 2020 1542	30	28 AUG 2020 1612	28 AUG 2020 1636	28 AUG 2020 1639	LBL 28 AUG 2020
11281227	28 AUG 2020	28 AUG 2020 1603	37	28 AUG 2020 1640	28 AUG 2020 1657	28 AUG 2020 1658	LBL 28 AUG 2020
11[illegible]1228	V1	31 Aug 2020 1015	40	31 Aug 2020 1107	31 Aug 2020 1130	31 Aug 2020 1145	MA 31 Aug 2020

JSN0489

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
11281209	V1	1045 27 AUG 2020	30	1122 27AUG2020	1150 27AUG2020	1152 27 AUG2020	ME 27AUG2020
11281212	V1	27 AUG 2020 1200	51	27 AUG2020 1251	27 AUG2020 1402	27 AUG 2020 1414	LBR 27AUG2020
11281213	V1	27AUG2020 1213	38	27 AUG2020 1251	27AUG2020 1412	27AUG2020 1414	LBR 27AUG2020
11281214	V1	27 AUG2020 1515	31	27AUG2020 1546	27AUG2020 1605	27AUG2020 1607	LBR 27AUG2020
11281216	V1	27 AUG 2020 1635	37	27 AUG2020 1712	27AUG 2020 1728	27AUG 2020 1730	LBR 27AUG2020
11281215	V1	27AUG 2020 1657	42	27AUG2020 1739	27AUG2020 1758	27 AUG 2020 1802	LBR 27AUG 2020
11281218	V1	27 AUG2020 1709	30	27 AUG 2020 1739	27 AUG2020 1759	27AUG 2020 1802	LBR 27AUG2020
11281217	V1	27 AUG 2020 1731	30	27AUG2020 1801	27 AUG2020 1818	27 AUG 2020 1819	LBR 27AUG2020
11281219	V1	28 AUG 2020 1007	35	28AUG2020 1042	28AUG2020 1107	28AUG2020 1109	LBR 28AUG2020

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001 **PI: Mark Koch, MD** **Site: 1128**
Laboratory: Covance **Sampling Type: Blood**

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128203	V1	1215 26Aug2020	~~20~~ 30	1245 26Aug2020	1250 26Aug2020	1300 26Aug2020	MK 26Aug2020
1128204 26 Aug 2020 MK	V1	1240 ~~1304~~ MK 26Aug2020	30	1335 26Aug2020	1348 26Aug2020	1401 26Aug2020	MK 26Aug2020
1128204 26 Aug 2020 MK	V1	1307 26Aug2020	30	1338 26Aug2020	1340 26Aug2020	1345 26Aug2020	MK 26Aug2020
1128205	V1	1527 26 Aug 2020	30	1616 26Aug2020	1619 26Aug2020	1620 26 Aug 2020	MK 26 Aug 2020
1128206	V1	1605 26Aug2020	30	1704 26Aug2020	1708 26Aug2020	1718 26Aug2020	MK 26 Aug2020
1128207	V1	1614 26Aug2020	30	1702 26Aug2020	1714 26Aug2020	1720 26Aug2020	MK 26 Aug2020
1128208	V1	1658 26Aug2020	30	1733 26Aug2020	1808 26Aug2020	1817 26Aug2020	AS 26AUG2020 MK 26Aug2020
1128211	V1	1011 27Aug2020	30	1036 27Aug2020	1122 27Aug2020	1124 27Aug2020	MK 27 Aug 2020
1128210	V1	27aug2020	30	1036 27Aug2020	1122 27 Aug 2020	1132 27 Aug 2020	MK 27 Aug 2020

JSN04491

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1192	V1	1037 25 Aug 2020	30	1140 25 Aug 2020	1750 25 Aug 2020	1808 25 Aug 2020	MR 25 Aug 2020
1128 1195	V1	1650 25 Aug 2020	30	1750 25 Aug 2020	1800 25 Aug 2020	1808 25 Aug 2020	MR 25 Aug 2020
1128 1196	V1	1753 25 Aug 2020	30	1826 25 Aug 2020	1825 25 Aug 2020	1828 25 Aug 2020	MR 25 Aug 2020
1128 1197	V1	1823 25 Aug 2020	30	1844 25 Aug 2020	1850 25 Aug 2020	1853 25 Aug 2020	MR 25 Aug 2020
MR 25 Aug 2020 1128 1194	V1	1823 25 Aug 2020	30	1904 25 Aug 2020	1908 25 Aug 2020	1922 25 Aug 2020	MR 25 Aug 2020
1128 1198	V1	1000 26 Aug 2020	30	1025 26 Aug 2020	1056 26 Aug 2020	1057 26 Aug 2020	MR 26 Aug 2020
1128 1199	V1	1119 26 Aug 2020	30	1156 26 Aug 2020	1210 26 Aug 2020	1215 26 Aug 2020	MR 26 Aug 2020
1128 1201	V1	1133 26 Aug 2020	30	1210 26 Aug 2020	1236 26 Aug 2020	1238 26 Aug 2020	MR 26 Aug 2020
1128 1202	V1	1134 26 Aug 2020	30	1218 26 Aug 2020	1238 26 Aug 2020	1240 26 Aug 2020	MR 26 Aug 2020

JSN0492

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001 **PI: Mark Koch, MD** **Site: 1128**
Laboratory: Covance **Sampling Type: Blood**

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1184	V1 25Aug2020	1136 25Aug2020	30	1208 25Aug2020	1219 25Aug2020	1228 25Aug2020	MR 25Aug2020
1128 1186	V1	1258 25Aug2020	30	1316 25Aug2020	1335 25Aug2020	1346 MR 25Aug2020	MR 25Aug2020
1128 1185	V1	1245 25Aug2020	30	1320 25Aug2020	1335 25Aug2020	1346 MR 25Aug2020	MR 25Aug2020
1128 1187	V1	1255 25Aug2020	30	1336 25Aug2020	1344 25Aug2020	1349 25Aug2020	MR 25Aug2020
1128 1189	V1	1436 25Aug2020	30	1548 25Aug2020	1555 25Aug2020	1550 25Aug2020	MR 25Aug2020
1128 1190 25Aug2020 MR	V1	1506 25Aug2020	30	1618 25Aug2020	1628 25Aug2020	1728 25Aug2020	MR 25Aug2020
1128 1188	V1	1532 25Aug2020	30	1610 25Aug2020	1626 25Aug2020	1728 25Aug2020	MR 25Aug2020
1128 1191	V1	1608 25Aug2020	30	1658 25Aug2020	1722 25Aug2020	1728 25Aug2020	MR 25Aug2020
1128 1193	V1	1620 25Aug2020	30	1658 25Aug2020	1728 25Aug2020	1728 25Aug2020	MR 25Aug2020

JSN0493

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001 **PI: Mark Koch, MD** **Site: 1128**
Laboratory: Covance **Sampling Type: Blood**

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
11281174	V1	1429 24 Aug 2020	30	1447 24 Aug 2020	1519 24 Aug 2020	1520 24 Aug 2020	MR 24 Aug 2020
11281173	V1	1428 24 Aug 2020	30	1447 24 Aug 2020	1519 24 Aug 2020	1520 24 Aug 2020	MR 24 Aug 2020
11281176	V1	1532 24 Aug 2020	30	1633 MR 24 Aug 2020	1637 MR 24 Aug 2020	1638 24 Aug 2020 MR	MR 24 Aug 2020
11281177	V1	1559 24 Aug 2020	30	1632 24 Aug 2020	1645 24 Aug 2020	1650 24 Aug 2020	MR 24 Aug 2020
11281178	V1	1725 24 Aug 2020	30	1740 24 Aug 2020	1742 24 Aug 2020	1750 24 Aug 2020	MR 24 Aug 2020
11291179	V1	1745 24 Aug 2020	30	1820 24 Aug 2020	1830 24 Aug 2020	1834 24 Aug 2020	MR 24 Aug 2020
11281182	V1	1057 25 Aug 2020	30	1135 25 Aug 2020	1148 25 Aug 2020	1154 25 Aug 2020	MR 25 Aug 2020
11281181	V1	1053 25 Aug 2020	30	1135 25 Aug 2020	1148 25 Aug 2020	1154 25 Aug 2020	MR 25 Aug 2020
11281183	V1	1114 25 Aug 2020	30	1208 25 Aug 2020	1219 25 Aug 2020	1228 25 Aug 2020	MR 25 Aug 2020

JSN04494

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001 **PI: Mark Koch, MD** **Site: 1128**
Laboratory: Covance **Sampling Type: Blood**

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1126 1165	V1	24 Aug 2020 0947	30	1040 24 Aug 2020	1044 24 Aug 2020	1045 24 Aug 2020	MG 24 Aug 2020
1128 1100	V1	24 Aug 2020 0944	30	1213 24 Aug 2020	24 Aug 2020	24 Aug 2020	MG 24 Aug 2020
1128 1167	V1	24 Aug 2020 1129	30	1243 24 Aug 2020	1235 24 Aug 2020	1257 24 Aug 2020	MG Aug 24, 2020
1128 1169	V1	1140 24 Aug 2020	30	1248 24 Aug 2020	1285 24 Aug 2020	1254 24 Aug 2020	MG 24 Aug 2020
1128 1168	V1	1202 24 Aug 2020	30	1350 MG 24 Aug 2020	~~1235~~ 1335 24 Aug 2020	1330 24 Aug 2020	MG 24 Aug 2020
1128 1171	V1	1304 24 Aug 2020	30	1332 24 Aug 2020	1354 24 Aug 2020	1356 24 Aug 2020	MG 24 Aug 2020
1128 1172	V1	1304 24 Aug 2020	30	1332 24 Aug 2020	1339 24 Aug 2020	1339 24 Aug 2020	MG 24 Aug 2020
1128 1170	V1	1315 24 Aug 2020	30	1354 24 Aug 2020	1354 24 Aug 2020	1424 24 Aug 2020	MG 24 Aug 2020
1128 1175	V1	1412 24 Aug 2020	30	1447 24 Aug 2020	1514 24 Aug 2020	1522 24 Aug 2020	MG 24 Aug 2020

JSN04495

Ex. 26

Brook Jackson

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Thursday, September 10, 2020 11:11 AM
To: Kandy Downs; Brook Jackson
Subject: **PLEASE READ** Source Completion & Clinical Conductor Visit Reconciliation Requirements

Importance: High

I wanted to send this as a reminder, Kandy, that we have to make sure our sites are completing all visits in Clinical Conductor (CC) BEFORE leaving for the day. Brook, I can show you how to check CC to ensure this is being done. I put an Outlook reminder on the calendar for my sites- not sure how you're doing it, Kandy, but this has helped some, but they do get behind still. We need to be adding this to our performance evaluations, please. Executive leadership will hold us all responsible if it's not getting done. Also Brook- please see the email below this that I sent out recently to everyone about these requirements.

Per a previous Daily Status Update by Mercedes:

Mercedes

- Pending visits in CC since 8/12. Yesterday, there are still 25 pending visits. If sites do not know how to complete these, reach out to Angela for guidance. See below. I only see two pending patients
    - Show the following still pending apts.
        - 8/1- all Burleson (see attachment)
        - 8/17- all Houston (see attachment)
        - If all of these aren't completed by EOB today (and pending apts from today moved over, there will be write-ups for the SOM and RD)
        - Please have your sites take care of them, and moving forward, you guys need to be checking the check-in/check-out for the current day and the day before when you send your daily update. If there are still pending apts at your sites when you send your 4:00 update, that is the perfect time to get on the phone to your site and get them to start moving apts over.

Thank you both,
Marnie

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Thursday, August 13, 2020 5:12 PM
To: Ventavia <ventavia@ventaviaresearch.com>
Subject: **PLEASE READ** Source Completion & CC Visit Reconciliation Requirements
Importance: High

Hello everyone,

Please make note of a few critical reminders and new instructions:

1. **ALL source documents MUST be completed in real-time with patients**, at the time of the visit- before leaving the patient's room. DO NOT delay completing source to the end of the day- we must be completing every blank, every footer, etc., at the time of the visit, with no exceptions. The patient chart should be completed so that by

the time one is done with the chart, it can easily be passed on to be QC'd, scanned into Complion, and then entered into eDC. And this applies to all studies, not just COVID. Please remember, this data has to be completed regardless- either on the frontend or the backend. The problem with choosing the backend, is now the time has passed so data or assessments have been forgotten, source may have already been scanned in, signatures were missed and now the investigator is not available to sign. This results in deviations, queries, and overall will jeopardize the integrity of the data and ultimately our reputation and future access to studies and thus revenue coming in.

2. Given the critical nature of this, patient charts will be spot-checked at all sites for "audit readiness" and if source is found to be incomplete, performance counseling will be issued.

***We MUST be audit-ready at ALL times**. The FDA can walk into a clinic tomorrow, completely unannounced, and review any chart they want to. Everyone should be leaving their clinic for the day knowing that patient charts can be reviewed at any time by anyone, and have no doubt that we would pass any surprise audit.

3. The same goes for **reconciling all visits in Clinical Conductor-** this must be done by the end of the day BEFORE leaving for the day. There should be no "pending" visits left on the calendar. This is crucial for many reasons but mostly to ensure adequate and timely study reimbursement, but also to ensure we all have real-time and accurate scheduling information.
4. Lastly, this is a new item that we are implementing immediately- we need to **capture race for all patients.** We already record this in our source documents, but we will be documenting this on the Patient Information Sheet that is completed on all patients so that we can upload this as well into Complion. I have revised the form to include this, below is the link to the new form in SharePoint:

https://netorg18834.sharepoint.com/:w:/g/EVJKnP9DI_xGoo7DXJrH7OsBGyPLSuKnARD3sOKedTrZuw?e=bvjYUw

Please let me know if you have any questions or concerns and please ACKNOWLEDGE that you have read this email.

Thanks all,

Marnie Fisher
Director of Operations, MBA, BSN, RN

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Cell Number: 817.269.3768
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https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

Ex. 27

To: Marnie Fisher[mfisher@ventaviaresearch.com]; Brook Jackson[bjackson@ventaviaresearch.com]; William Jones[wjones@ventaviaresearch.com]
Cc: Mercedes Livingston[mercedeslivingston@ventaviaresearch.com]; Olivia Ray[oliviaray@ventaviaresearch.com]; Kristi Raney[kristiraney@ventaviaresearch.com]
From: Kandy Downs[kdowns@ventaviaresearch.com]
Sent: Thur 9/24/2020 8:52:58 PM (UTC)
Subject: Pfizer C4591001_Koch|1128, Fuller|1085, Tran|1096_COVID-19 Symptom Surveillance Log
Pfizer_C4591001_COVID Surveillance Review Log_19AUG2020.docx

Here is the Weekly COVID log, dated 19Aug2020- but none of the sites have been using this.

This needs to be placed in the charts and goes with the NTF for being not used, but weekly trialmanager reviews, are, were being conducted.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group

1307 8th Ave Suite #202

Fort Worth, TX 76104

Cell Number: 817-269-5997
eFax Number: 817.394.1901

Email: kdowns@ventaviaresearch.com

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From: Kathryn Weems <kathrynweems@ventaviaresearch.com>
Sent: Tuesday, September 22, 2020 1:28 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>
Subject: Fw: Pfizer C4591001_Koch|1128, Fuller|1085, Tran|1096_COVID-19 Symptom Surveillance Log

Resending! See email below as well.

Kathryn Weems
Regulatory Coordinator
Ventavia Research Group

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VRG VENTAVIA RESEARCH GROUP
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From: Kathryn Weems <kathrynweems@ventaviaresearch.com>
Sent: Tuesday, September 22, 2020 11:44 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>; William Jones <wjones@ventaviaresearch.com>
Subject: Fw: Pfizer C4591001_Koch|1128, Fuller|1085, Tran|1096_COVID-19 Symptom Surveillance Log

Hello,

It seems that I did initially create a COVID-19 Symptom Log, but it was buried during review. I sent it out to the lead CRCs (which, at the time, Becca was helping out with this study) and Dana, but never heard back and thus... it was left untouched.

Please review to see if this solves any issues with COVID-19 symptom surveillance.

Regards,

Kathryn Weems
Regulatory Coordinator
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From: Kathryn Weems
Sent: Wednesday, August 19, 2020 11:05 AM
To: Rebecca Iacullo <rebeccaiacullo@ventaviaresearch.com>; Katherine Benitez <katherinebenitez@ventaviaresearch.com>; Thea Sonnier <tsonnier@ventaviaresearch.com>
Cc: Dana Duvak <danaduvak@ventaviaresearch.com>
Subject: Pfizer C4591001_Koch|1128, Fuller|1085, Tran|1096

Hi ladies!

You requested for me to create a COVID symptom review log for eDiaries. On Becca's recommendation (thank you Becca!!), I based it on the RSV surveillance log from the maternal RSV study. I have created and attached the initial draft based on the protocol and the Trialmanager user guide. If you note anything that should be added or removed, please send back with the document and tracked changes on (or highlighted so I can see the change), and explanation on why on the email body! That way I can solve any issues quickly!

If you all are fine with the new source and its good to be used for this study, I will finalize this study source.

Regards,

Kathryn Weems
Regulatory Coordinator
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C5691001

Weekly Subject COVID Symptom Review Log

Date of Vaccination 1: _____________ Date of Vaccination 2: _____________ **TrialMax reports are to be printed once page is completed**

Study Week	Site Team Date of Review	Initials of Reviewer	Any COVID Symptoms or events entered in eDiary?	If no/incomplete data entered, subject was called, or if subject received any tests (NAAT, Rapid Antigen, molecular diagnostic), enter here.
			◻ None ◻ A diagnosis of COVID-19 ◻ Fever ◻ New or Increased Cough ◻ New or Increased shortness of breath ◻ Chills ◻ Any other respiratory symptom of concern ◻ New or increased muscle pain ◻ New loss of taste/smell ◻ Sore Throat ◻ Diarrhea ◻ Vomiting	
			◻ None ◻ A diagnosis of COVID-19 ◻ Fever ◻ New or Increased Cough ◻ New or Increased shortness of breath ◻ Chills ◻ Any other respiratory symptom of concern ◻ New or increased muscle pain ◻ New loss of taste/smell ◻ Sore Throat ◻ Diarrhea ◻ Vomiting	
			◻ None ◻ A diagnosis of COVID-19 ◻ Fever ◻ New or Increased Cough ◻ New or Increased shortness of breath ◻ Chills ◻ Any other respiratory symptom of concern ◻ New or increased muscle pain ◻ New loss of taste/smell ◻ Sore Throat ◻ Diarrhea ◻ Vomiting	
			◻ None ◻ A diagnosis of COVID-19 ◻ Fever ◻ New or Increased Cough ◻ New or Increased shortness of breath ◻ Chills ◻ Any other respiratory symptom of concern ◻ New or increased muscle pain ◻ New loss of taste/smell ◻ Sore Throat ◻ Diarrhea ◻ Vomiting	
			◻ None ◻ A diagnosis of COVID-19 ◻ Fever ◻ New or Increased Cough ◻ New or Increased shortness of breath ◻ Chills ◻ Any other respiratory symptom of concern ◻ New or increased muscle pain ◻ New loss of taste/smell ◻ Sore Throat ◻ Diarrhea ◻ Vomiting	

Date report was printed: __ __/__ __ __/__ __ __ __ COVID-19 Symptom/Event Review Report Printed by: ________

Subject Initials/Number: __ __ __ / ____________

Page __ of __

C4591001

Weekly Subject COVID Symptom Review Log

Ensure that the Schedule of Activities are reviewed for the subject if they are confirmed to have COVID symptoms or events. During the 7 days following each vaccination, potential COVID-19 symptoms that overlap with solicited systemic events (ie, fever, chills, new or increased muscle pain, diarrhea, vomiting) should not trigger a potential COVID-19 illness visit unless, in the investigator's opinion, the clinical picture is more indicative of a possible COVID-19 illness than vaccine reactogenicity. Subjects will be prompted to report COVID-19 symptoms or events until Visit 6 is completed, in which the site will either collect the e-diary at this visit or assist the participant to delete the application. Use the comments below to address any other issues when filling out the COVID Symptom Review Log. This could include events such as:

- Subject is contacted by phone.
- Subject sent alert to site via e-mail.
- Potential COVID-19 Illness Visit is scheduled
- Potential COVID-19 Illness Visit is scheduled but not completed
- If any further information is collected from subject upon contact.
- Potential COVID-19 Illness Visit not scheduled; subject unable to complete visit (scheduling issue)
- Potential COVID-19 Illness Visit not scheduled – data entry error in eDiary (symptoms/event entered in error)
- PI determined that an assessment was not needed.

Additional notes (if applicable):

Ex. 28

Daily Status Calls-Notes and Action Items

9/17/2020 Action Items

Kandy

- QC both unblinded logs at KEL and FW
- **Get ARL's screening visits canceled so Becca can immediately QC Keller**
- **Get Plano's visits handled by Precilia so Jill can immediately QC Keller**
- Check with William:
    - FDA training
    - Should HOU stop enrolling, ask William please
- Put a plan in place to schedule weekly touchpoints with your PI's
- Talk with JP
    - What did she mean that "Ventavia is going to get what's coming to them"?
        - Let he know how concerned Dr. B is about that
    - Go over Peppler's concerns-comments about being unhappy, unsupported, etc.
    - Go over professionalism, growth, examples that have been given
    - Have KB as a witness and make sure this convo is all documented and sent to us so we can make an informed decision (write up vs termination)

Marnie

- **Talk to Dr. Fuller about pausing enrollment**
- **Dana needs to help QC FW (we will push back novavax start a week or two, if needed, bc she will ask)**
- **JV needs to help QC FW**
- Get Mer out there when it's FDA ready
- Make sure both RD's set up a schedule to do weekly touchpoints with their PI's-oversee this

Brook

- Admin needs to be at desk at all times. Get coverage for restroom and lunch breaks. No folders of W9's there (explain to Becky), make sure nothing else is in sight.
    - Go through FDA training (auditor walks in, ask for identification, etc.)
- Talk to Jen about how we are putting subject's safety at risk and get specifics and report back to us asap
- Let Koch know that we are pausing enrollment
- Get Mer out there when it's FDA ready
- Put a plan in place to schedule weekly touchpoints with your PI's

Olivia

- Call Chrystal to stop scheduling
- Cancel visit 1's after 11am today and the rest of the week and next week (FW and KEL)
- Put patients on the schedule after 9/28

9/16/2020 Action Items

Mercedes

- Get references for Tiara
    - If good, then get a call with Medix

Brooke

- Make sure Keller and FW have the Firecrest amendment 6 training completed by this morning
- Speak to Jaz and have her go to Chrystal about communication with calling pts
- Speak to Jen Vasilio about overseeing Chrystal
- Continue to monitor recruitment efforts for FW and KEL-COVID

Marnie

- Call J.Valo and see what she wants, let her know when she has questions to come to Marnie first

Kandy

- Continue to monitor recruitment efforts for HOU-COVID

9/15/2020 Action Items

Kandy

- Focus on recruitment this week for HOU (Covid)
- Put the AZ issue in an email to all of us so we can come up with wording on how to respond to this
- Get hard confirmation from Univision about going live on Thursday
- Talk to Christine about sub-leasing contract
- Talk to Alma about going back to Burleson, work with Marnie/Brook about FW exit plan
- Talk to Jill about goal date of 9/21 for PM start, in the meantime, work with Dana on looking at checklists (tailoring it to fit mat rsv studies), PM job description, etc.
    - Get Precilia added to the other studies
- Talk to Cordy about Arlington (fast and furious, no mileage) vs Burleson (slower)
- Send Univision email statement to Katie Buchanan

Marnie/Brook

- Keep a close eye on Katie/Keller's enrollment numbers, she needs to continue to try and schedule the full 60 for the week. If she's having a challenge with less CRC's, she needs to loop us in before Chrystal decides to stop scheduling patients.
- Work with Chrystal this week to get numbers up, check on CC list for 16 and 17 yr olds (or waiting list?)
- Focus on the recruitment this week for FW and KEL (Covid)
- Help with Alma exit plan

Mercedes

- Check with Kate on Amend. 6 ICF
- Give directive to sites and recruiters if we can start enrolling 16 and 17 yr olds

  - ICF IRB approved and received by sites
  - Amend 6 firecrest training completed
- Follow up with reg person about hours and schedule

Olivia

- Find Medix contract
- Find HOU lease

9/14/2020 Action Items

Olivia

- Get with Katie about bamboo HR and salary info in the system
- Get with Katie about moving PI/Sub-I/Pre-screening physician onboarding to the RD's on the checklist (CV's, trainings, etc.)
- Run email by her

Kristi

- Call Pam about reaching out to the news stations in DFW
- Write up something generic for news stations

Kandy

- Let sites know to reach out to James/Burt when they need help filing so they can knock it out
- Identify a scanner
- Get Univision ad ran today
- Get in touch with Christine to see if Lizatte can call Syan Rhodes about a follow up story, and then all other HOU sites
- Stay on your SOM's to get the missing certifications, PI/SubI stuff done **this week**
- Talk to Christine about extending Tony's contract if he can
- Talk to Becca about staying in ARL for right now, and have her go to Dallas one day this week to QC

Marnie/Brook

- Can you have J. Valo work in GRA on Wednesday
- Get with Katie Buchanan to add J.Valo to timeco
- Jailyn-help email, make sure it was dealt with (with Jen Vasilo), please get Jailyn in a better place (documented games plan to get things distributed)
- Let sites know to reach out to James/Burt when they need help filing so they can knock it out
- Reach out to Jen Vasilo about Jerred's load and let him know about Katie Buchanan pulling him to work with her (newsletter, bamboo HR/timekeeping system, etc.)
- Identify a scanner
- Get with Angela about adding onboarding newhire for the next two weeks, OT approved if needed (submit to Marnie or Mer for approval??)
- Stay on your SOM's to get the missing certifications, PI/SubI stuff done **this week**

Mercedes

- 9/9-WEA, 9/12-DAL, 9/13-WEA, DAL, HOU-Pending Visits in CC
- Call Andrea back about raising the offer

9/11/2020 Action Items

Kandy

- Precillia review to Mer
- Tell Christine to make second interview rounds and narrow it down
- Talk to Mark about helping with reg

Marnie/Brook

- Get reviews to Mercedes (April, Kati D, Rebecca Mateos)
- Talk to Katie Benitez and Jen Vasilio about getting all EDC and internal queries done by EOB today or EOB tomorrow

Mercedes

- Work with Shannon to get freezer excursion reported to the sponsor
- Have Shannon talk to Dr. Pero about freezer being unplugged and moved, and the consequences it caused
- Have Shannon expense her hotel room
- Call DFW candidates
- Resend W9 email
- Send out email for mat rsv sites to send email when baby is born, RD, SOM's, etc.
- Send an offer to Kati D's referral and FW admin

9/10/2020 Action Items

Marnie/Brook

- Marnie to follow up with Kate Weems again, discuss her attitude and phone etiquette (conversation with Mercedes yesterday) find out what's going on with her- where's the "old happy Kate".
- Brook to reach out to Kate Weems to schedule one-on-one introduction and request Complion training- Brook will get a feel for what's going on with Kate as well.
- Stay on top of Chrystal today to ensure recruitment scheduling goals are being met, per Kristi's instruction and if not, what's her game plan:
    - This week- Houston 40, FW 60, Keller 60
    - Next week- Houston 100, FW 60, Keller 60
    - Following M-W- Houston 100, FW and Keller at least schedule 25 per day.
- Follow-up with Chrystal to see if they have reached out to other offices in the building to recruit.

Kandy

- QC MAT RSV charts in FW

- Continue reviewing resumes and will forward those recently reviewed to Kristi/Mercedes

Mercedes

- Follow-up with candidates (Lori/Kati D referral- will make offer)
- Shadow Angi and Alicia in Keller- review some of their charts

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9/9/2020 Action Items

Mercedes

- Reach out to Katie Buchanan to get a job description to send to Anne as a Research Assistant
- Get with Angela to go through all maternal visits and see that they are being completed correctly
- Contact hospitals to see what we have to request to get the congenital heart screening document that has Pulse Ox on it
- Follow-up with maternal sites to get IMPALA updated

Marnie/Brooke

- Ensure the review that was completed with Anne yesterday was sent to Katie Buchanan for filing
- Speak with Anne about regulatory background
- Kandy review to Mercedes
- Reach out to Jen Vas to see if FW needs another mini fridge/-20 freezer for FW
- Talk to Jennifer Valo about maintenance Project Manager role- starting next week
    - Need to get with Dana on templates and checklists for the role
- Send email to project managers (Jennifer, Jill and Dana) reminding them to introduce themselves when reaching out for the first time, be kind
    - Role is to build a relationship between the sites
- Send out a company wide email regarding Project Managers
    - Dana over adult COVID
    - Jill over Maternal studies
    - Jennifer Valo over maintenance studies
- Send a shout out for Kati D enrolling 4 maternal patients yesterday

Kandy

- Create job description/step by step guide as to what makes a good Research Assistant
- Precillia review to Mercedes
- Jennifer Payne review to Mercedes
- Will look at resumes
- Get mini fridge and freezer from room 4 in FW to Arlington 2nd location
- Prioritize Becca on getting the job outlines for positions

- Reach out to Jill to see if she had
- Look for staff on Indeed, etc for the following openings
    - CRC for Plano, Arlington, RA (Arlington), Keller, FW
    - Recruiter for HOU
- Follow-up with FW to see if Thea hand cut was written up

9/8/2020 Action Items

Mercedes

- Send Dana the job description for the PM role for starting tomorrow, she needs to send a daily report everyday before she's done, create a checklist from the script, and SIV's should be first priority (by the 23rd or before), and if she can't get to the source she needs to wave the white flag so we can have Becca step in and do it. Have convo with her about working from home and kid's distractions.
- Ask Marnie if she sent the SIP email.

Kandy

- Work on Univision thing
- Get reviews to Mercedes

9/4/2020 Action Items

Kandy

- Radio script/TV ad, send to K/M/O

Olivia

- Send VRG logos to Kandy

9/3/2020 Action Items

Mercedes

- Get Angela ready to go remote next week
- Get resume from Kati Dykes to call and interview

Marnie

- Let Kate know that writing emails or slacks about x, y, z is a time-waster and she is spinning her wheels. She is not in a position to be giving her opinion of what we should be doing as a company (take the study, don't take the study, site too busy, questioning why the owners are asking her to do a reg packet as a priority when the reg letter said it could be done in 10 days, etc.). Writing these long emails is taking time away from all the other stuff she should be doing and is super stressed about. She is OOTO until Tuesday.
- Send an email company-wide looking for very strong CRC's and shout out to everyone about how we are building infrastructure, etc.

- Type up email regarding mileage
- Get with admins at each covid site about purchasing bins/baskets (make sure they look ok/nice) for bottled water and pre-packaged snacks to have available for patients during high enrolling study days (order everything online to always have available and in sight for patients)

Kandy

- Get with Christine to talk to Tran about the space (hire more staff, control employees better, not having to go up and down stairs to see patients,
- Send Telemundo pricing to us
- Get HOU ad to us today
- Talk to Christine about getting their OT under control once enrollment stops
- Have Jerred create a cheat sheet for all sites regarding saving an email in a pdf
- Tell Becca to keep her emotional feelings out of emails, try to stick to the facts
- Christina-review, need to get it ready, address the toll issue
- Talk to Jill about PM role and getting her moved over, also about making sure christina is being trained and shadowed

9/2/2020 Action Items

Mercedes

- Talk with William about his recommendations for QC employees
- Log into Firecrest to see if we have a radio ad already approved by Pfizer
- Talk to Haily, Elyza, and Jessica today so we can make a decision on Erin
- Oversee the Inv onboarding email
- Pending visits in CC in ARL the last couple of days
- Send an email chain to get status update at end of each day, how many they got to, etc. Any glaring findings? Set an alarm.

Marnie

- Talk to JV to try and consolidate all her doc appts into one day, make sure she's clocking out for these appts-if it continues, let's loop Marisa and Mercedes in. Document and give to KB for filing.
- Look at reviews and get a game plan
- Keep an eye on Anne's QC'ing, look at her chart that she has QC'd to check her work
- Review Kandy's SO verbal warning doc before submitting to K.Buch
- Look for KB's email and about certifications and Kate Weems email re: Inv onboarding

Kandy

- NTF for Keller temp log excursion
- Look at reviews and get a game plan
- Complete a SO verbal warning document re: Anne and have it reviewed by Marnie quickly
- Call HOU to see what is going on with the news spot
- Look for KB's email and about certifications Kate Weems email re: Inv onboarding

9/1/2020 Action Items

Kandy

- Look at resumes for CRC's for almost all sites

Kristi

- Email KB about setting up mediation session

Mercedes

- Tell Jen Vas to turn in verbal to KB, not have Niki sign

8/31/2020 Action Items

Olivia

- Reactivate HOU ad?

Mercedes

- Tell Erin we are still interviewing
- Pending visits in CC

Kandy

- Have Cordy do the first vaccine on the phone with her
- Dallas-IRB documentation emails
- Keller phlebotomist email-follow up with Katie (Cara Lopez-rate)
- Let Olivia know if we need to activate HOU ad tonight
- Help with Katie B email re: investigators

8/27/2020 Action Items

Mercedes

- Reach out to Erin re: medical records
- Go through Kate's email and reach out to Becca about source (Pfizer Mat RSV and COVID)
- Kate-OT approved, talk to her about training William
- Final interview/vet Erin McLeod, approval to hire for FW, 57k

Olivia

- Reach out to JV, DD re: new roles
- Send role email to Kandy to the chain
- Oversee covid-19 recruitment numbers while Kristi is out

Kandy

- Reach out to Christine, Lizatte, Jill re: new roles
- Go to sub-I mess of an email and handle Marnie's sites also
- Angi training for Pfizer mat rsv over the weekend

- Reach out to KB in KEL about EDC entry

8/26/2020 Action Items

Mercedes

- Reply to email KEL about month to month lease
- Change in OM to always schedule PSSV's as early in the window as possible

Marnie

- Pending visits in CC-see Mer's email (DAL, ARL, HOU)
- Check on unblinded situation for KEL
- Work with Jen Vasilio about Saturday clinic for covid-19
- Need to make KEL and FW understand that in order to get the $500 stipend, they need to work whatever it takes (late nights and Sat clinics) to get close to their enrollment goal each week

Kandy

- Pending visits in CC-see Mer's email (DAL, ARL, HOU)
- Call Kate and ask her to resubmit PSF for COVID-19 (from CC) ASAP
    - IRB approved autoimmune diseases, incl T1 diabetes (but this is incorrect and needs to be removed)
- Work with Chrystal to figure out how to identify and contact any subjects we inadvertently PS failed bc of T1 diabetes and re-PS for scheduling

8/25/2020 Action Items

Mercedes

- Call Deedra and offer ARL
- Get with Marnie and decide who needs to get added to Keller PSSV

Marnie

- JV-speak about racial comment, have a verbal coaching/mentoring moment (racial tendency and negative attitude towards leadership) (ex. Slave driver and "being illegal" vs undocumented)
- Get with Mer and decide who needs to get added to Keller PSSV
- Let Alma know that Mer will handle BUR tomorrow
- Get with your COVID sites and have them call and move up anyone who is scheduled past two weeks out, bc study might close
- Work with FW on getting more scheduled to get 60 this week, have Chrystal email Meagan and ask her to check the info@ven email every 24 hours and forward all participant emails each day (whenever Meagan plans to work (at night, mid-day, whatever). If Chrystal or other recruiters need to login to get emails sooner, the password is Research1!
- **Be the VRG employee whisperer!!! haha**

Kandy

- Get with your COVID sites and have them call and move up anyone who is scheduled past two weeks out, bc study might close
- Work with JP on SAE narrative

8/24/2020 Action Items

Kristi

- Task Becca with calling healthcare facilities surrounding KEL, FW, HOU for reaching out to their employees about the study, all school districts (for their employees), churches, daycare employees

Mercedes

- Make sure KEL schedules PSSV this morning (make sure to tell them to mention access to minorities and healthcare workers)
- Call Arturo to speak on behalf of FW and KEL and minorities
- Pending visits in CC Aug 20th

Olivia

- Boost old HOU ad on FB
- Do HOU ad again for CRC

Marnie

- Check on PSSV time today for Novavax (make sure to mention access to minorities and healthcare workers), grab JV or Angela for any VRG specific questions
- Offer the $500 weekly stipend to all FW clinic employees willing to work OT/Sat clinics to get these 60 in, manager needs to collect the employees' names and submit these stipends to payroll at each run, cc Kristi, Olivia, Mercedes, so payroll knows its legit
- Thea-speak to her about urgent matters, she should have told us RIGHT way, we could have had all weekend to schedule and plan for this week. This is a HUGE deal. Verbal warning. Now we might have lost 20 pts for this week. This was hundreds of thousands of dollars on the line. If she emailed it on Friday, the email needs to be forwarded to us.
- Get Janssen game plan going for season 2 participants (49 pts, 3 hours visits, starting Sep 7th?)
- Let your sites know, anything that would be printed and put in hard reg binder, needs to be uploaded to Complion
- Pending visits in CC Aug 20th

Kandy

- Find another HOU CRC
- Send over recent onboard lists
- Speak with Alma about helping in FW until we have someone else hired
- Get on Dallas/Arlington email to figure out sub-I signatures
- Let your sites know, anything that would be printed and put in hard reg binder, needs to be uploaded to Complion

- COVID 1001 DOA log updates-HOU
- Pending visits in CC Aug 20th

8/21/2020 Action Items

Kristi

- Send email out to all remotes to see if they need a new scanner

Olivia

- Amend Indeed ad to include ARL
- Send email to JV with updates

Marnie

- Go read Olivia's Becca email carefully

Kandy

- Order the drop-down desks
- Get with all sites about ordering scanners
- Work with Shannon on sending PD's to the IRB, and creating a dummy chart
- Talk to Christine
    - Turn in the $1000 bonuses to payroll each payroll week and she can cc Kristi/Olivia/Mercedes so payroll knows it's legit
    - See about putting someone in Tran's office to get more covid pts scheduled
    - Work on messaging and over scheduling to compensate for huge no shows
    - Call Garza's pts who have appts to see if they want to come to VRG after for an appt
    - Lottery thing
    - Offer pizza
    - Order the fridge

8/20/2020 Action Items

Kandy

- Call HOU RD to see if interested in contract QC position, get rate, ask about travel to DFW if she were to get the RD position
- Get HOU to create a schedule for COVID enrollment
- Create a site plan to recognize holes

Marnie

- Get office organized, get desk setup-bring in Angela's son to help with all of this
- Create a site plan to recognize holes
- Speak to Katie about overseeing both sites for a few weeks

Mercedes

- Get Brook's offer out

8/19/2020 Action Items

Kristi & Olivia

- Speak with Becca about new role

Kandy

- Find an employee to hire to upload Complion for COVID-19
- Find or delegate someone to find a high-speed/high volume scanner to purchase for sites that need it
- Finish write up and send to everyone for review
- Get with HOU regarding 5 pending visits in CC from 8/17

8/18/2020 Action Items

Mercedes

- Pending visits in CC since 8/12. Yesterday, there are still 25 pending visits. If sites do not know how to complete these, reach out to Angela for guidance.
- Think about Regional Director vs Support Specialist title, and who, internally, would be a good fit

Marnie

- Talk to your COVID sites
    - As soon as they have a no show, call the recruiter and tell them to fill the spot
    - Schedule 20 Mon and 20 Tues, and 8 pts for Wed (in case recruitment cannot replace N/S's on Mon/Tues) If we hit our 40 by Tues, then move Wed's 8 pts to the following week.
    - Pull up CC and account how many are short
- Pending visits in CC since 8/12. Yesterday, there are still 25 pending visits. If sites do not know how to complete these, reach out to Angela for guidance.
- Talk to Jennifer Vasscilio about possibly going to HOU
- Talk to maternal calls, on call phones need to be with them at all times. Mom's are starting to deliver. Patients, staff, doctors are to ONLY call on call phone. Not personal phones!
- Follow up with newhire (Angi's friend—can't remember her name)
- Think about Regional Director vs Support Specialist title, and who, internally, would be a good fit

Kandy

- Talk to your COVID sites
    - As soon as they have a no show, call the recruiter and tell them to fill the spot
    - Schedule 20 Mon and 20 Tues, and 8 pts for Wed (in case recruitment cannot replace N/S's on Mon/Tues) If we hit our 40 by Tues, then move Wed's 8 pts to the following week.
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- Think about Regional Director vs Support Specialist title, and who, internally, would be a good fit

8/17/2020 Action Items

Mercedes

- Confirm with Pfizer about what constitutes a week, can we get a head start on a Friday (as long as we don't go over 40 the following week), what is the window of IP
- Confirm with Pfizer that time IP needs to stay out and give proper directive to Marnie and Kandy, so they can let their unblinded staff know
- Find Olivia's email and get a plan for VRG, send to Kristi/Olivia
- Find Olivia's email and get a response back to Pfizer, cc Kristi/Olivia
- CC-visits still pending from the 7th, and maybe earlier. That's just the last day I finally stopped checking.
- Get Burt's help to get the laptops set up in FW

Marnie

- Go over reconsent ICF process at all sites, not the admin's responsibility. The lead needs to manage this. She can assign the admin to put the ICF in the chart, but the admin realistically has no idea if a new consent has arrived.
- Find Olivia's email and get a plan for VRG, send to Kristi/Olivia
- Find Olivia's email and get a response back to Pfizer, cc Kristi/Olivia
- CC-visits still pending from the 7th, and maybe earlier. That's just the last day I finally stopped checking.
- Let your SOM's know that sometimes we need to use kindness to deal with difficult patients (purchase lunch, a coffee, small gift card, apologize, etc.) Make it right when they are in the office, don't wait until they leave upset and go write reviews or report us to the IRB, FDA. Customer service is everything.

Kandy

- Find Olivia's email and get a plan for VRG, send to Kristi/Olivia
- Find Olivia's email and get a response back to Pfizer, cc Kristi/Olivia
- CC-visits still pending from the 7th, and maybe earlier. That's just the last day I finally stopped checking.
- Let your SOM's know that sometimes we need to use kindness to deal with difficult patients (purchase lunch, a coffee, small gift card, apologize, etc.) Make it right when they are in the office, don't wait until they leave upset and go write reviews or report us to the IRB, FDA. Customer service is everything.
- Get Dallas set up so Christina can go over and help ARL a couple of days a week

8/14/2020 Action Items

Olivia

- Check on FB commenting
- Clinical Conductor
    - Send instructions on how to pull visit statuses in CC

Mercedes

- Go over ediary issue with Kandy onsite in FW
- Offer OT to anyone who can come in and get things caught up on Sat

Marnie

- ~~Cordy send all logs to KD to verify it's correct~~
- Katie
    - Make sure they know to get their 64 in next week since they have no usable drug right now (24 leftover from this week and then the new 40 next week)
- Dana
    - Discuss scheduling friends or couples together, then take away the other spot. For example: 9 and 10 appt can turn into 2 at 9am and 0 at 10am
- Becca-stern talking to about the behavior, she needs to be acting as a mentor at any site, never singling or excluding people, remaining in KEL for COVID pts
- Nika
    - Move her to GV as soon as the new lady is ready to go on her own
- Make sure all sites have same complion plan in place for KEL, HOU, and FW
    - Initial and dating any blanks as everything might have already been uploaded
    - Have all sites give an update by EOB
    - Tomorrow needs to be worked to get everything caught up
- Offer OT to anyone who can come in and get things caught up on Sat

Kandy

- ~~Look over KEL's logs to ensure it's correct~~
- Make sure HOU has same complion plan in place as KEL and FW
    - Initial and dating any blanks as everything might have already been uploaded
    - Have all sites give an update by EOB
    - Tomorrow needs to be worked to get everything caught up
- Offer OT to anyone who can come in and get things caught up on Sat

8/13/2020 Action Items

Kristi

- Reach out to Kandy if you haven't received the GSK Mat recruitment email by EOB
- Dig around CC to track recruiters' record
    - Recruiters calling out vs taking incoming calls

Olivia

- FW recruiters
    - Take ad down

- HOU Staffing
    - Take the ad down for CRC
    - Keep ad for recruiter

Mercedes

- Get in touch with Arturo to check on Keller's IP
- Talk to JV
    - First round of interviews, give her specific questions to weed out, forward her any contenders from Indeed
    - Respect she needs to work remote
    - Help with WEA or maternal trainings as needed
    - Get Nikki trained on medical records ASAP, so she can start taking over next week
    - Still remain MR backup
    - Start assisting with source creation and PSF review/approval
    - Mercedes will also see what things you can assist her with
    - I really think there was more—but you will need to ask Mercedes to see what we are missing

Marnie

- Email ALL SITES for ALL VISITS: DO NOT LEAVE THE ROOM UNTIL SOURCE IS COMPLETE-Send email, write up if caught, FDA auditor will walk through the door at any second, high profile study, but this needs to be the standard for ALL STUDIES/ALL VISITS, no exceptions
- Check Clinical Conductor still pending visits for all sites
- Remind sites about drug waste
- Reminder (if needed), they have spent the last 6 months with coordinators MAYBE seeing one or two patients a week, yes it's busy, but come on now
- Talk to your sites about capturing race in CC when a patient comes in-mass email is fine
- Talk to Dr. Robbins about above issue, per Mer's email
- Talk to Angi, Becca, Nika, Cordy, etc, regarding gossip issue-replay she has been hired as an SOM for Dallas, she is training in KEL, they need to take her under her wing and mentor her
- Talk to Nika/Cordy about 3 pts she turned down, remind Cordy she can't make decisions without running them through Katie
- Get Katie back in Keller to manage COVID trial, find coverage for Grapevine
- Dana
    - Remind her about Nikki and the medical records
    - Pull Linda from lab and assign someone else
    - GSK MAT ICF issue email, possible trust issues with Linda and Jailyn
- Run complion upload by Kate and Mercedes, then give directive to site
- Chrystal-make sure FW gets the rest of their covid pts scheduled for the week

Kandy

- Talk to Christine
    - Create a same day list of patients to be "on call" for covid visits

- GSK Recruitment Plans-questions-send to Kristi
- Send email that Spanish translator doesn't have to be on the DOA Log so sites are aware
- Check Clinical Conductor still pending visits for all sites
- Remind sites about drug waste
- Reminder (if needed), they have spent the last 6 months with coordinators MAYBE seeing one or two patients a week, yes it's busy, but come on now
- F/U with HOU regarding COI for Tran

8/12/2020 Action Items

Kristi

- Send Jasmine resume to Katie Buchanan

Marnie

- Talk to JV
    - First round of interviews, give her specific questions to weed out, forward her any contenders from Indeed
    - Respect she needs to work remote
    - Help with WEA or maternal trainings as needed
    - Get Nikki trained on medical records ASAP, so she can start taking over next week
    - Still remain MR backup
    - Start assisting with source creation and PSF review/approval
    - Mercedes will also see what things you can assist her with
    - I really think there was more—but you will need to ask Mercedes to see what we are missing
- Talk to your sites about capturing race in CC when a patient comes in
- Dana
    - Remind her about Nikki and the medical records
    - Make sure Nadia is being utilized to full potential
    - **All COVID sites need to have a QC station prior to uploading into Complion (Alma)**
- Direct sites to do easier process for complion upload
- Watch Thea like a hawk

Kandy

- Talk to KEL and HOU about ediary issue
- **NIKA/ANNE: All COVID sites need to have a QC station prior to uploading into Complion**
- Direct sites to do easier process for complion upload
- Watch Thea like a hawk
- Call James if you have not talked to him already about EDC (214 208 0320)
- Complete CAPA for FW

8/11/2020 Action Items

Mercedes

- Call Arturo to confirm that drug received for KEL this week, can be utilized this week
- Make sure Angie sends resumes over

Marnie

- Cordy
  - Check in on her, see if there is another unblinded that can replace her so she can get back to recruiting
- Talk to Nika
  - Get Anne on the phones today, along with Alaina (do not pull them off the phones)
  - Check on drug
  - Make sure they are knocking out new drug in 2.5 days (16/16/8)
  - Make sure Katie is in Grapevine on Fri afternoon, so get help from someone else if needed
  - Look at schedule ad drug, day by day and confirm if you need the additional help. If not, then please don't pull them (Alma, Becca, Kati D, etc.)
  - Go over ediary issue/falsifying data, etc.
- Talk to Becca
  - Help create the schedule for KEL COVID
- Talk to Dana
  - Go over Mer's email re: COVID scheduling
  - Look at schedule ad drug, day by day and confirm if you need the additional help. If not, then please don't pull them
  - Go over ediary issue/falsifying data, etc.
- Chrystal
  - Tell her to change the visit time to 2 to 2.5 hours
  - She needs to train recruiters to start capturing race in CC
- Talk to JV
  - First round of interviews, give her specific questions to weed out, forward her any contenders from Indeed
- Talk to your sites about capturing race in CC when a patient comes in

Kandy

- Nikki-make sure unblinded for COVID (to free up Jailyn to see maternal pts), blinded for all maternal/pedi, eventual training on Medical Records
- Talk to Nadia (with Marnie)-can we get Nadia switched to onboarding/admin duties/take tasks over from Katie Buchanan for the next couple of months until Dana can take it back over. If she is, then please facilitate the process between KB and NM and the FW site to get this started.
- Talk to Christine
  - About the Complion upload station
  - Go over ediary issue/falsifying data, etc.
- Talk to your sites about capturing race in CC when a patient comes in

8/10/2020 Action Items

Olivia

- Hiring-Indeed Ads-Tweak to add the following
    - HOU-CRC, FW-CRC, KEL-2 CRC, 3-5 years' experience

Mercedes

- Get resume for Decatur for possible cord blood pickup and maybe CRC assisting if KD friend does not work out
- Interview Eddie
- Get Lorena onboarded for PRN calling/scheduling and cord blood pickup
- Draft up mat rsv deviation response

Marnie

- Get resume over from Kati Dykes-possible CRC asst
- Call Nika/Katie:
    - Anne needs to focus on scanning into Complion as much as possible this morning
    - Need to start scheduling starting Tues afternoon for new covid pts
- Call FW:
    - Get a game plan in place to get Complion caught up in EOB today
    - Move patients within their window to fit more COVID pts
    - Let Dana know Mer needs to know when they have a pedi blood draw due to so many deviations, so she can go up and draw
- Call Jennifer Valo that she needs to be in FW the rest of the week
- Call Chrystal and:
    - Direct John to call for KEL
    - Cordy cannot be responsible for KEL recruitment right now
    - Tell her OT is approved for nights and weekends so we can get spots filled
    - Let her know Shannon (anyone else), must call AND schedule
    - If newbies have questions, put them on hold and ask a seasoned employee, bc everyone needs to be trained and, on the phones, as soon as they can

Kandy

- Call Shannon and have her help call for COVID sites
- Follow up with Ashley-would she be a better fit in FW long term?
- Jasmine follow up
- Make sure Niki is trained on unblinded for COVID (to free up Jailyn), medical records and blood draws for maternal studies, train others on blood draws on pedis

Ex. 29

Shoot, I don't have that invite. 7:59 AM

I'll fwd it, and see about a other laptop for you 8:00 AM

Tue, Sep 15, 7:32 AM

Good morning, did Keller still need help with scanning again today? Were u able to get through much? 7:32 AM

I didn't get one thing scanned. Katie handed me 5 charts that were "urgently" needed by Sponsor and not one had been QC'd. 7:52 AM

Oh! Okay. FW is behind in QC now. Do u want to go back to Keller to help scan and I can QC in FW? Or which would you prefer? 7:54 AM

I feel like either one is a trap 😂 7:55 AM

I will go to either. 7:56 AM

Lol right. I will go to FW since I need to take the binders I picked up from Weatherford and then we can do our regulatory call at 1230 by zoom 7:59 AM

Should we review reg processes before hiring? 8:35 AM

Ex. 30

BASE AGREEMENT

BETWEEN

ADVANCED TECHNOLOGY INTERNATIONAL (ATI)
315 SIGMA DRIVE
SUMMERVILLE, SC 29486

AND

Pfizer, Inc.
235 E 42nd St,
New York, NY 10017

MEDICAL CBRN DEFENSE CONSORTIUM (MCDC) BASE AGREEMENT NO.: 2020-532

Authority: MCDC Other Transaction Agreement (OTA) No. W15QKN-16-9-1002 and 10 U.S.C. § 2371b, Section 815 of the 2016 National Defense Authorization Act (NDAA), Public Law (P.L.) 114-92.

This Agreement is entered into between the Advanced Technology International hereinafter referred to as the "Consortium Management Firm (CMF)," and Pfizer Inc., hereinafter referred to as "Project Agreement Holder." This Agreement constitutes the entire understanding and agreement between the parties with respect to the subject matter hereof and supersedes all prior representations and agreements. It shall not be varied except by an instrument in writing of subsequent date duly executed by an authorized representative of each of the parties. The validity, construction, scope and performance of this Agreement shall be governed by the laws of the state of South Carolina, excluding its choice of laws rules.

ADVANCED TECHNOLOGY INTERNATIONAL

(Signature)

[redacted]
Jul 20 2020

(Name & Title)

(Date)

FOR THE PROJECT AGREEMENT HOLDER
Pfizer Inc.

[redacted]

(Signature)

[redacted]

(Name & Title)

July 20, 2020

(Date)

Article I. SCOPE OF THE AGREEMENT

Section 1.01 Background

The U.S. Army Contracting Command-New Jersey (ACC-NJ) is entering into a Section 815 Prototype Other Transaction Agreement (OTA) with the Medical CBRN Defense Consortium, c/o Advanced Technology International 315 Sigma Drive, Summerville, SC 29486. The Joint Project Manager for Medical Countermeasure Systems (JPM-MCS) through the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) seeks to collaborate with the MCDC to carry out a coordinated research and development program. An OTA is being proposed with the purpose of conducting Research and Development into medical, pharmaceutical, and diagnostic technologies to enhance mission effectiveness of military personnel. The MCDC was formed in response to the Government's expressed interest to engage with an industry consortium comprised of traditional and nontraditional government contractors, small and large businesses, for-profit and not-for-profit entities, academic organizations and their affiliates for the purpose of entering into an OTA for prototype projects.

Under the OTA and associated awards, the Government, along with the non-government members from the MCDC, shall perform coordinated planning and research and development prototype efforts designed to encompass the areas contained within the scope of this OTA as listed in Article I, Section 1.03.

Section 1.02 Definitions

"Academic Research Institution" means accredited institutions (colleges, universities or other educational institutions) of higher learning in the U.S.

"Agreement" refers to the Base Agreement between the Medical CBRN Defense Consortium (MCDC) Consortium Management Firm (CMF) Advanced Technology International (ATI) and the Project Agreement Holder.

"Agreements Officer (AO)" is the U.S. Army Contracting Command – New Jersey's warranted Contracting Officer authorized to sign the final OTA for the Government.

"Agreements Officer Representative (AOR)" is the individual designated by the Government on a per project basis to monitor all technical aspects and assist in agreement administration of the specific project; the AOR shall only assist in agreement administration of the specific project to the extent delegated such administration authority in writing in the AOR delegation letter by the responsible Agreements Officer.

"Basket" is an electronic file containing proposals that have been submitted by MCDC Members in response to Requests for Prototype Proposals (RPP), reviewed by the Government, and favorably evaluated in accordance with the procedures outlined in Section 1.03 of this Article.

"Cash Contribution" means a MCDC member organization's financial resources expended to conduct a project awarded under this Agreement. The cash contribution can be derived from MCDC member organization funds or outside sources or may also come from non-federal contract or grant revenues or from profit or fee on a federal procurement contract. A MCDC member organization's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds can be utilized as a cash contribution provided those funds identified by the MCDC member organization are to be spent on the conduct of a project's Statement of Work. Prior IR&D will not be considered as part of the MCDC member organization's cash or in kind contributions nor will fee be considered on the Project Awards that include cost sharing. Cash contributions include the funds a MCDC member organization will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), subcontractor efforts expended on a project, and restocking the parts and material consumed under a project.

"Consortium Management Firm (CMF)" refers to the organization acting on behalf of the MCDC to execute and administer the efforts under the Other Transaction Agreement for this program as defined in the specific agreement

entered into between the MCDC and the CMF. The current CMF is Advanced Technology International (ATI). The MCDC reserves the right to replace the CMF at any time.

"Cost Share" means resources expended by the PAH on the proposed project SOW and subject to the direction of the AOR. There are two kinds of cost share: cash contribution and in-kind contribution. Cost Share may only be proposed and collected on cost-reimbursement type agreements.

"Contracting Activity" means an element of an agency designated by the agency head and delegated broad authority regarding acquisition functions. It also means elements or another agency designated by the director of a defense agency which has been delegated contracting authority through its agency charter.

"Date of Completion" is the date on which all work is completed or the date on which the period of performance ends.

"Development" means the systematic use, under whatever name, of scientific and technical knowledge in the design, development, test, or evaluation of an existing or potential new technology, product or service (or of an improvement in an existing technology, product or service) for the purpose of meeting specific performance requirements or objectives. Development includes the research functions of design engineering, prototyping, and engineering testing.

"Effective Date" means the date when this Agreement is signed and executed by the Agreements Officer for the Government.

"Government" means the US Government and its departments and agencies.

"Government Fiscal Year" means the period commencing on October 1 and ending September 30 of the following calendar year.

"In Kind Contribution" means the MCDC member organization's nonfinancial resources expended by the MCDC member organization to conduct a project, such as wear and tear on in-place capital assets like machinery or the prorated value of space used for the conduct of a project, and the reasonable fair market value (appropriately prorated) of equipment, materials, and other property used in the conduct of the project.

"JPM-MCS" means the Joint Project Manager-Medical Countermeasure Systems Office created for the advanced development of medical countermeasures for chemical and biological defense. The JPM-MCS is also the program management office for this overall effort. The JPM-MCS includes an array of stakeholders involved in the development of prototype hardware, software, and system technologies.

"Milestone" means a scheduled event signifying the completion of a major deliverable or a set of related deliverables.

"Medical CBRN Defense Consortium" is the consortium formed by industry in response to the Government's expressed interest to quickly provide the warfighter with safe and effective chemical, biological, radiological, and nuclear countermeasures. The MCDC is comprised of Traditional and Nontraditional Defense Contractors, including small and large (other than small) businesses, for profit, and not for profit entities, and academic research institutions. The MCDC was originally named the National Chemical and Biologic Defense Consortium.

"MCDC Executive Committee" is the Executive Committee, comprised of Traditional and Nontraditional Defense Contractors, including small and large businesses, for profit and not for profit entities, and academic research institutions.

"MCDC Members" means the Nontraditional and Traditional Defense Contractors, including small and large businesses, for profit and not for profit entities, and Academic Research Institutions that are members in good standing of the MCDC.

"Nontraditional Defense Contractor" with respect to applicable authority, means an entity that is not currently performing and has not performed, for at least the one-year period preceding the solicitation of sources by the Department of Defense for the procurement or transaction, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to section 1502 of title 41 and the regulations implementing such section.

"Other Transaction Agreement (OTA)" refers to the Section 815 Other Transaction Agreement between the Government and the MCDC by its Consortium Management Firm, Advanced Technology International, Agreement No. W15QKN-16-9-1002.

"Other Transactions for Prototype Projects" refers to this type of Other Transaction Agreement (OTA). Section 815 of Public Law 114-92 authorizes the use of OTAs, under the authority of 10 U.S.C. 2371(b), under certain circumstances for prototype projects directly relevant to enhancing the mission effectiveness of military personnel and supporting the platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces. This type of OTA is treated by DoD as an acquisition instrument, commonly referred to as an "other transaction" for a prototype project or Section 815 "other transaction".

"Parties" means the Consortium Management Firm, Advanced Technology International, and the Project Agreement Holder where collectively identified and "Party" where each entity is individually identified.

"Payable Milestone" means that once a milestone has been met (see definition of "milestone"), the Government can approve payment to the MCDC of a predetermined dollar amount in relation to performance of a particular project under the Other Transaction Agreement.

"Program Manager" means the Technical Administrator for the Program (located at the JPM-MCS) responsible for Government oversight of the MCDC OTA program.

"Project" refers to the scope of work being completed under a Project Agreement.

"Project Agreement (PA)" means that agreement between the MCDC, by its CMF, and the MCDC member entity whose proposal is evaluated and competitively selected by the Government for funding, establishing the scope of work, terms and conditions for the MCDC member entity performance and payment under the Government funded project. Project Agreements shall comply with all provisions contained within the OTA and any other supporting documents referenced therein. The Project Agreement is initiated by the CMF based on the Technical Direction Letter sent by the Government to the CMF.

"Project Agreement Holder (PAH)" means the MCDC member entity issued a Project Agreement by the CMF.

"Technical Direction Letter (TDL)" is a Government document to be issued to the CMF reflecting the Government's decision to select and fund all or part of a particular proposal submitted by a MCDC member or team of MCDC members through the RPP process conducted under this OTA. The TDL shall establish the scope of work, terms and conditions for performance and payment and include the MCDC member proposal selected for Government funding. Where a specific Government agency laboratory, test facility, center or other location will be used by the MCDC member entity in performance of the Project Agreement, it will be identified and the cost of such use, whether Government-contributed or MCDC member reimbursed, will be identified in the TDL.

"United States Army Contracting Command – New Jersey Contracting Activity" (ACC-NJ) means the contracting activity who is designated as the lead Government organization in charge of executing the Program.

"White Paper" means a document limited to a few pages prepared and submitted by a MCDC member(s) in response to a Government solicitation issued under the terms and conditions of the OTA that briefly describes and summarizes a technology idea or concept for an indicated research area in a Government-specified format. The White Papers are evaluated by the Government to determine whether submission of a full proposal on the summarized concept or idea might be warranted. To the extent that a MCDC member(s) desires to include

proprietary information in the white paper it shall be identified and marked in accordance with the terms for protection of information under Article VIII. Confidential Information.

Section 1.03 Scope

The Government in conjunction with the MCDC member entities shall perform a coordinated research and development program designed to support the DoD's medical, pharmaceutical, and diagnostic requirements as related to enhancing the mission effectiveness of military personnel. The mission of JPM-MCS is to provide the U.S. military forces and the nation safe, effective, and innovative medical solutions to counter Chemical Biological Radiological and Nuclear (CBRN) threats. Under the OTA and associated Project Agreements, the Government along with the Consortium member entities, shall perform coordinated planning and research and development prototype efforts in support of the JPM-MCS mission through the development of products in three (3) major Medical Countermeasure Systems (MCS) objective areas:

Detection: Systems and devices to identify CBRN agents and assist in making medical decisions
Prevention: Prophylaxis, pretreatment, and post-exposure prophylaxis
Treatment: Therapeutics (post-exposure, post-symptomatic)

The Government will determine which endeavors to pursue and projects to fund. At any time throughout the term of the OTA, the Government may address the needs for the desired MCS objective areas or other related Government needs as they arise. The MCDC and the Government agree that other organizations and agencies within the U.S. Government may participate in the collaborative activities through a Memorandum of Agreement or other such arrangement. It is anticipated that these other organizations may include JPEO-CBD and DTRA.

Request for Prototype Proposal (RPP) Process:

Once the Government identifies a need under one of the MCS objective areas above, the Government will issue a Request for Prototype Proposal (RPP). The RPP will include a Request for White Papers (RWP) and/or a Request for Prototype Proposal (RPP) to the Consortium Management Firm (CMF). Due dates will be indicated for each. The CMF shall in turn issue a similar request to MCDC's member entities, for which the Government will review and evaluate all responses. The Government will be solely responsible for evaluation of the white papers and/or proposal submissions, as applicable. If the RPP includes a RWP, only members submitting white papers will be permitted to submit full proposal submissions. Based on the evaluation of the white papers, the Government will make a recommendation on whether the member should or should not submit a full proposal submission. Any member submitting a white paper, regardless of the Government's recommendation, may submit a proposal.

MCDC member white papers and proposals shall be submitted to the CMF in accordance with the RPP instructions which will include evaluation criteria and a Statement of Work (SOW) template on the due date indicated in the RPP. The CMF will review white paper and proposal submissions for completeness and format compliance. The CMF shall in turn prepare and transmit MCDC's member's white papers and proposals to the Government for evaluation. The Government will be responsible for technical evaluation and selection of the projects from the proposals submitted. The CMF will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government Agreement Officer will review this assessment and make the final determination regarding whether the negotiated project cost is fair and reasonable. All Project Agreements will be subject to discussions/negotiations and proposal updates, as appropriate, prior to execution.

Once all steps are complete, the Government will issue a Technical Direction Letter (TDL) to the CMF for the authorization and execution of the selected project to be performed by the selected MCDC's member entity(ies). Once the CMF receives notification of selection of a project for funding via TDL, the CMF will enter into a Project Agreement with the MCDC member.

A modification will be included with the TDL, which will include the funding for the negotiated and agreed-upon project. After receipt of the TDL and review and execution of the funding modification, the CMF shall enter into a Project Agreement (PA) with MCDC member whose project was selected. MCDC CMF shall administer the Government-funded Project Agreements. The Government's designated Agreements Officer Representative (AOR)

for the specific project will supervise the technical work performed by MCDC's member entity in execution of the PA. The Government reserves the right to revise the terms and conditions of these projects in accordance with Article III, Section 3.04.

Placement in the Electronic "Basket File":

Qualifying proposals, not eligible for current funding, may be entered into an electronic basket and subject to award for up to thirty-six (36) months. The RPP will contain the available ratings and their definitions to be assigned to proposals as a result of the technical evaluation as well as which specific ratings will qualify a proposal for inclusion in the Basket. The Government reserves the right to determine which, if any, proposals are to be selected according to the published criteria.

Once in the Basket, a proposal may be identified for award by the Government based on Government need and availability of funding. The Government reserves the right to 1.) request that the MCDC member who submitted the identified proposal, scale or otherwise adjust the original proposal, and to 2.) fund all or part of the identified proposal. The MCDC member will have an opportunity to update their proposal, as applicable, if selected from the basket. The Government will review any updated information provided by the MCDC member and/or CMF. Upon the Government's decision to fund such a proposal from the Basket, the CMF will receive notification of the award decision through a TDL whereupon the CMF will enter into a Project Agreement with the indicated MCDC member as required.

A selected proposal will reside in the Basket for thirty-six (36) months from the date the corresponding RPP is closed unless funded or the submitting MCDC member requests in writing beforehand to have it removed.

SBIR Phase III Project Requests

It will be incumbent upon the MCDC member, on their own with some general support and guidance from the CMF, to find a Government Technical POC with both (1) available funding and (2) an interest in furthering technology developed under a current or prior SBIR project. Upon doing so, the Government Technical POC will coordinate the feasibility of placing the award under the OTA with the Government AO and OTA Program Manager and the following areas will be considered when making a determination for appropriateness of award under the OTA:

- How the proposed effort derives from, extends, or logically concludes efforts performed under prior SBIR funding agreements;
- How the proposed effort fits within the definition of a prototype effort related to medical, pharmaceutical, and diagnostic technologies to enhance mission effectiveness of military personnel in accordance with the statutory requirement;
- How the proposed effort fits within the overall scope of work and the goals and objectives of the OTA.

Should the Government AO and the OTA Program Manager determine it is appropriate to award the SBIR Phase III under the OTA, the Government AO will send a proposal request to the MCDC member through the CMF, as is standard for any Government request under the OTA. The CMF will provide a cost analysis summary to the Government Agreements Officer (AO) for consideration in the Government's award determination. The Government will evaluate the proposal, conduct any necessary negotiations through the CMF, and make an award determination. If the Government makes the determination to award to the MCDC member, the Government AO will issue a TDL letter to the CMF, resulting in the issuance of a Project Agreement between the CMF and MCDC member.

SBIR Phase III awards under this Agreement shall include the Data Rights provisions and Data Rights granted to the MCDC member contained within Article XI of this Agreement. All administrative, reporting, and other aspects of awards made for SBIR Phase III efforts under this Agreement will be in accordance with the terms and conditions of the OTA. MCDC Members must have been awarded and performed under a previous SBIR Phase I and/or Phase II contract in order to qualify for SBIR Phase III award under this Agreement.

Section 1.04 Goals/Objectives

The following goals/objectives will be pursued through the execution of the OTA:

Accelerate the development of mission critical technologies in the areas of concern from applied research into advanced development.

Deliver therapeutic MCM prototypes targeting viral, bacterial, and biological toxin targets of interest to the DOD. MCM prototypes are drug products that have completed all or part of the activities required to support FDA licensure. This may include meeting warfighter requirements of protection against an aerosolized route of exposure.

Deliver enabling technologies that will support the development and regulatory review of MCM prototypes. The enabling technologies can include animal models of viral, bacterial or biological toxin disease and pathogenesis (multiple routes of exposure), assays, diagnostic technologies or other platform technologies applicable to development and regulatory review of MCM.

Develop prototype candidates for the prophylaxis, treatment and diagnosis of Chemical threats. This will include diagnosis of, and prophylaxis and treatment for, exposure to traditional and emerging chemical nerve agent threats, as well as other emerging chemical threat agents other than nerve agents.

Develop prototype candidates for the prophylaxis, treatment and diagnosis of Radiological and Nuclear threats. This will include prototype candidates for diagnosis of, and prophylaxis and treatment for Acute Radiation Syndrome.

Develop soldier-carried autoinjector delivery devices for single drug administration. Develop soldier-carried autoinjector delivery devices for administration of two or more drugs.

Develop vaccine-manufacturing platforms that offer early stage manufacturing flexibility and diversity using a deep knowledge of protein(s) expression in a biological system that is reproducible and scalable, and preferably with direct FDA experience. The goal is to manufacture and test identified protective molecule(s) and target molecule(s) (along with associated reagents and standards) in multiple scalable, flexible manufacturing platforms encompassing a diverse array of manufacturing systems (e.g., insect, mammalian, live viral, plant, *E.coli*, yeast, etc.) for use in appropriate animal model(s) and in Phase 1 trials.

Pharmaceutical development will address the FDA Animal Rule, as appropriate.

Utilize adjuvants and excipients supporting the ability to develop up to 300,000 equivalent doses within 60 days at clinical quality.

Support a family of systems diagnostic approach that increases the speed, accuracy, and confidence of agent identification and disease diagnosis. Diagnostic areas include those for organisms that circulate freely and at relatively high numbers at or near the onset of symptoms, organisms that circulate in low numbers early in infection but then integrate with host cells, organisms that have significant genomic diversity from strain to strain, and non-BW agents such as toxins/chemical agents/radiological agents that do not replicate and require low quantities to cause illness.

Support the Defense Biological Products Assurance Office (formally the Critical Reagents Program), the principal DoD resource of high quality, validated, and standardized biological reference materials, reagents, and assays, as necessary.

DoD Advanced Development and Manufacturing Capabilities: To facilitate lessons learned and to ensure DoD MCM product development schedules are not impacted, the consortium will consider Advanced Development and Manufacturing (ADM) capability contractors for biologics manufacturing activities for monoclonal antibodies, vaccines, and recombinant proteins may utilize the DoD funded facility.

Pursue collaborative research with non-traditional technology providers in a manner that enables effective transition of technologies to Government prototyping programs during any phase of life cycle support (affordability, manufacturability, sustainment, etc.).

Section 1.05 Reports

The MCDC member organizations conducting projects in accordance with this Agreement shall maintain records of the activities performed and funding expended under the projects and the results of any studies analyses, tests, and other investigations conducted. Based on the progress of the funded projects and other information known to the AO or authorized designee, the MCS Program Office shall review the relevant projects throughout the period to determine if any changes to planning or budget are required. If such a change is expected which will cause a need to modify the OTA, the Technical Direction Letter or an individual Project Agreement may be modified to incorporate such changes. The AO is the only authorized representative of the Government who may make modifications to the OTA. PAHs shall submit the following reports to the CMF who will review and provide one cumulative report detailing status of all funded projects to the MCS Program Office.

a.) Project Agreement Quarterly Report. The report will have two major sections:

(i) Technical Status Report. The technical status report will detail technical progress to date and report on all problems, technical issues or major developments during the reporting period. Each of the topics described below shall be addressed for the effort performed:

(1) A comparison of actual accomplishments with the goals and objectives of the project established for the period.

(2) Reasons why established goals and objectives were not met, if appropriate.

(3) Other pertinent information including, when appropriate, analysis and explanation of cost variances.

(4) A cumulative chronological list of written publications in technical journals. Include those in press as well as manuscripts in preparation and planned for later submission. Indicate likely journals, authors, and titles.

(5) Papers presented at meetings, conferences, seminars, etc.

(ii) Business Status Report. The business status report shall provide summarized details of the resource status of the Project Agreement, including the status of the contributions by all participants. This report will include a quarterly accounting of current expenditures. Any major deviations from the agreed to project plans shall be explained with discussion of proposed actions to address the deviations. The report will also include an accounting of interest earned on Government Funds, if any. It is not expected that any interest will accrue under the Project Agreement(s), as milestone payments will be tracked and adjusted accordingly. In any event, the Government reserves the right to require interest amounts in excess of $250 per year to be remitted to the US Treasury.

b.) Annual Technical Report. Annual technical reports are required for projects whose periods of performance are greater than one year. The PAH's report will provide a concise and factual discussion of the significant accomplishments and progress during the year covered by the report.

c.) Final Technical Report.

(i) Final Technical Report (FTR). A Final Technical Report shall be submitted to the CMF within thirty (30) calendar days of the completion of the Project Agreement. This report will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of the effort. Each of the topics described above shall be addressed as appropriate for the effort performed. Upon receipt, the AOR will review and provide any comments within 30 days. If necessary, the PAH will update the FTR within 30 days of receipt of AOR's comments. Once the CMF has informed PAH that the FTR has been approved by the AOR, the PAH shall forward a copy of the FTR to the Defense Technical Information Center, Attn. DTIC-O, 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060-6218.

(ii) Format. The cover and title page shall be Standard Form (SF) 298, Report Documentation Page. Item 13 of the form should contain a 100 to 200 word abstract summarizing technical progress during the reporting period. Style should be third person singular using past tense. Jargon, special symbols or notations, subscripts, mathematical symbols or foreign alphabet letters are not permitted. All pages should be prepared for acquisition and distribution by the Defense Technical Information Center (DTIC). All pages should be good quality for copying purposes. The report shall be prepared in accordance with American National Standards Institute (ANSI) document Z39.18-1987, "Scientific and Technical Reports: Organization, Preparation, and Production," which may be obtained from American National Standards Institute Incorporated, 1430 Broadway, New York, NY, 10018. The FTR front page shall be marked in a conspicuous place with a distribution statement to denote the extent of its availability for distribution, release, and disclosure without additional approvals or authorizations.

d.) Final Business Status Report. The final business status report shall provide summarized details of the resource status of the Project Agreement, including the status of the contributions by all participants. This report will include a final accounting of cumulative expenditures. If a project is terminated prior to the end of a quarter or a year and sufficient funding is available, the PAH, through the CMF, must submit a final technical and business status report in the same format as detailed herein.

Note: Deficiencies in regulatory reports must be adequately assessed by the Government, MCDC and the individual performer, or consortium as a whole, to come to resolution.

Article II. TERM

Section 2.01 The Term of this Agreement

The period of performance for this Agreement is from the effective date, which is the date of last signature, to April 7, 2036. If at any time funds expended exceed the amount obligated on a Project Agreement prior to the expiration of the term, the Parties have no obligation to continue performance and may elect to cease their efforts at that point. Provisions of this Agreement, which, by their express terms or by necessary implication, apply for periods of time other than specified in Article II herein, shall be given effect, notwithstanding this Article.

Section 2.02 Termination of this Agreement by Mutual Agreement

Except for the rights and obligations with respect to proprietary information and/or specific intellectual property agreements between or amongst the Government, the CMF and the MCDC member organizations, unless extended by mutual written agreement of the Parties, this Agreement shall automatically terminate by written agreement of the Parties. Unless otherwise directed by the AO through the CMF, individual Project Agreements pursuant to this Agreement shall also terminate upon the termination of this Agreement.

Section 2.03 Termination Provisions

Subject to a reasonable determination that the program, or a project funded under the program, will not produce beneficial results commensurate with the expenditure of resources, the Government may terminate performance of work under this OTA or a specific project, in whole or in part, if the AO determines that a termination is in the Government's interest. The AO shall terminate by delivering to the MCDC through its CMF a Notice of Termination specifying the extent of termination and the effective date.

After receipt of a Notice of Termination, and except as directed by the CMF, the PAH shall immediately proceed with the following obligations, regardless of any delay in determining or adjusting any amounts due:

(1) Stop work and direct its subawardees to stop work as specified in the notice.

(2) Place no further subagreements or orders (referred to as orders in this clause) for materials, services, or facilities, except as necessary to complete the continued portion of the project.

(3) Terminate all orders to the extent they relate to the work terminated.

(4) Assign to the Government, as directed by the AO, all right, title, and interest of the PAH under the orders terminated, in which case the Government shall have the right to settle or to pay any termination settlement proposal arising out of those terminations.

(5) With approval or ratification to the extent required by the AO, the CMF may settle all outstanding liabilities and termination settlement proposals arising from the termination of orders; the approval or ratification will be final for purposes of this clause.

(6) Provide CMF, and/or obtain from the subawardees under the terminated portion of the Agreement a transfer of title to the following where applicable and deliver to the Government --

(i) The fabricated or unfabricated parts, work in process, completed work, supplies, and other material produced or acquired for the work terminated; and

(ii) The completed or partially completed plans, drawings, information, and other property that, if the order had been completed, would have been required to be furnished to the Government.

(7) Complete performance of any work not terminated, if applicable.

(8) Take any action that may be necessary, or that the AO may direct through the CMF, for the protection and preservation of the property related to this project that is in the possession of the PAH(s) or any subawardee and in which the Government has or may acquire an interest.

(9) Use commercially reasonable efforts to sell, as directed or authorized by the CMF, any property of the types referred to under Article II. Section 2.03 Termination Provisions, (6)(i) and (ii); provided, however, that the PAH:

(i) is not required to extend credit to any purchaser and

(ii) may arrange for the subawardee who was performing the terminated work to acquire the property under the conditions prescribed by, and at prices approved by, the CMF.

(iii) will in no event be required to continue with such efforts for more than three (3) months after notice by the CMF to sell or disposition such property.

(10) The PAH has no obligation to continue to cost share on the terminated project or terminated portion of the project.

The requirement for at least 1/3 cost share of the total project cost by the PAH is assessed prior to award. In the event that during the course of the performance of the Project Agreement any of the parties to the Project Agreement believe the cost sharing funds available will be insufficient, the PAH shall notify the CMF within twenty-five (25) days of the event that gave rise to the insufficient cost sharing funds. CMF will notify the Government within five (5) days of receiving such notice from the PAH. The Government will determine whether it is in its best interest to either renegotiate the scope and/or terms of the Project Agreement to meet the cost share requirement or terminate the Project Agreement in whole or in part.

The proceeds of any transfer or disposition of project property will be applied to reduce any payments to be made by the Government under that particular project, including credited to the price or cost of the work, or paid in any other manner directed by the CMF.

In the event of a termination of the Project Agreement, the Government shall have patent rights as described in Article X, Patent Rights, and rights in Data as described in Article XI, Data Rights. Failure of the PAH and Government to agree to an equitable adjustment shall be resolved pursuant to Article VII, Disputes.

Section 2.04 Termination Cost

The CMF will negotiate with the Government and PAH in good faith equitable reimbursement for work performed toward accomplishment of the task or tasks of individual projects. The Government will allow full credit for the Government share of the obligations properly incurred by a PAH prior to termination. Costs incurred by a PAH during a suspension or after termination of a project are not allowable unless the CMF expressly authorizes them in either the notices of suspension, termination, or subsequently. Other PAH's costs incurred during a suspension or after termination which are necessary and not reasonably avoidable are allowable if:

(a) The costs result from obligations which were properly incurred by the PAH before the effective date of the suspension or termination, are not in anticipation of it, and in the case of a termination, are non-cancellable; and

(b) The costs would be allowable if the project was not suspended or the award expired normally at the end of the funding period in which the termination takes effect.

Section 2.05 Close-out Procedure.

If the Government funds an individual Project Agreement and then subsequently terminates the agreement or the requirements of the agreement are met, the following closeout procedures apply:

(a) Definitions.

(i) "Closeout" – the process by which the Government and CMF determine that all applicable administrative actions and all required work have been completed by the PAH.

(ii) "Date of Completion" – the date on which all work is completed or the date on an amendment thereto on which the period of performance ends.

(iii) "Disallowed costs" – those charges that the Government or its representative determines to be unallowable, in accordance with the terms and conditions stated in this Agreement.

(b) Upon request, the Government shall make prompt payments to the PAH through the CMF for allowable reimbursable costs under the MCS Project Agreement being closed out.

(c) The PAH shall immediately refund any balance of unobligated (unencumbered) cash that the CMF has paid and that is not authorized to be retained by the PAH for use in the performance of the Project Agreement.

(d) The CMF shall obtain from the PAH within 90 calendar days after the date of completion of an MCS Project Agreement all financial, performance, and other reports required as a condition of the MCS Project Agreement. The CMF may grant extensions when requested by the PAH.

(e) When authorized, the CMF shall make a settlement for any upward or downward adjustments to the Government's share of costs after these reports are received based on final, actual expenditures in accordance with the Termination Costs provision of the Agreement.

(f) Quick close-out procedures similar to FAR 42.708 shall be followed.

(g) The PAH shall account for any property received from the Government.

Section 2.06 Stop Work

As directed by the AO, the CMF may, at any time, by written order to the PAH, require the PAH to stop all, or any part, of the work called for under this Agreement or any Project Agreement for a period of 90 days after the written order is delivered to the PAH, and for any further period to which the parties may agree. The order shall be specifically identified as a stop-work order issued under this section. Upon receipt of the order, the PAH shall immediately comply with its terms and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage. Within a period of 90 days after a stop-work is delivered to the PAH, or within any extension of that period to which the parties shall have agreed, the CMF shall either:

(a) Cancel the stop-work order; or

(b) Terminate the work covered by the Project Agreement as provided in Article II, Term and Termination.

If a stop work order issued under this clause is canceled, the PAH shall resume work. The CMF shall make an equitable adjustment in the delivery schedule or Project Agreement estimated cost/price, or both, and the Government's share of the Project Agreement shall be modified, in writing, accordingly, if—

(1) The stop-work order results in an increase in the time required for, or in the PAH's cost properly allocable to, the performance of any part of the Project Agreement; and

(2) The PAH asserts its right to the adjustment within 30 days after the end of the period of work stoppage; provided, that, if the Government decides the facts justify the action, the Government through the MCDC CMF may receive and act upon a proposal submitted at any time before final payment under the Project Agreement.

If a stop work order is not canceled and the work covered by the Project Agreement is terminated in accordance with Article II, the MCDC CMF shall work with the PAH to negotiate an equitable reimbursement in accordance with Article II. Section 2.03, Termination Provisions.

Article III. MANAGEMENT OF THE PROJECT

Section 3.01 The Medical CBRN Defense Consortium (MCDC)

The MCDC, as defined in the OTA, was formed to work with the Government and provide input in developing technologies to support the Department of Defense's (DoD) medical, pharmaceutical, and diagnostic requirements as related to enhancing the mission effectiveness of military personnel ultimately resulting in fully executed research and development prototype projects selected by the Government. Every Member in this MCDC is independent of the other, and there is no affiliation between the MCDC members within the definition of 13 C.F.R. 121.103 of the Federal Small Business Regulations and no such affiliation is intended either by the formation or implementation of the MCDC.

As appointed by the MCDC Executive Committee, the CMF has the authority to execute the Other Transaction Agreement (OTA) on behalf of the MCDC and has the responsibility for day to day overall administration of this Agreement, subject to the supervision of the MCDC Executive Committee.

Section 3.02 The following MCDC decisions are subject to the ACC-NJ approval:

1. Changes to the MCDC Articles of Collaboration if such changes substantially alter the relationship of the MCDC and the Government as originally agreed upon when the OTA was executed;
2. Changes to, or elimination of, any ACC-NJ funding allocation to any MCDC Member as technically and/or financially justified.

Section 3.03 Management and Project Structure

Technical and project management of the coordinated research program established under this Agreement shall be accomplished through the management structures and processes detailed in this Article.

The Government competitively selected the MCDC, organized by its Consortium Management Firm Advanced Technology International, a Section 501(c)(3) nonprofit organization. MCDC has entered into an agreement with Advanced Technology International authorizing Advanced Technology International to enter into this OTA as the consortium manager, engage in overall day to day management of the MCDC under the guidance of and as designated by the MCDC Executive Committee, including technical, programmatic, reporting, financial, administrative and contractual matters and administer Project Agreements required for performance under this OTA.

As established by funded projects under the OTA, the Government Program Manager shall fully participate in the appropriate program technical meetings held by the MCDC. The AORs and Other Government personnel, as deemed appropriate, also may participate in the technical portion of these meetings.

Section 3.04 Modifications

As a result of scheduled meetings, end of program reviews, or at any time during the term of the OTA, research progress or results may indicate that a change in the OTA's scope, objectives or Term would be beneficial to program objectives. Recommendations for modifications, including justifications to support any changes to the OTA Scope, will be documented in a letter and submitted by the PAH to the CMF, who will then forward it to the Program Manager with a copy to the AO. This documentation letter will detail the technical, chronological, and financial impact of the proposed modification to the OTA. The Program Manager shall be responsible for the review and verification of any recommendations to revise or otherwise modify the OTA Scope or other proposed changes to the terms and conditions of the OTA and subsequently this Agreement.

With regard to projects the Government determines to fund as a result of the RPP process specified in the Agreement Scope, any PAH recommendations for modifications, including justifications to support any changes to the funded projects, will be documented in a letter and submitted by the CMF to the AO with a copy to the Government Agreements Officer Representative designated for the particular project. The AO shall be responsible for review of proposed changes and for all modifications to the terms and conditions of the project awards. The CMF shall modify the Project Agreement(s) in the event of any such modifications or changes to the project.

Management of Projects

(1) Performance of the work on each project is subject to the technical direction of the AOR designated in the Project Agreement. For the purposes of this clause, technical direction includes the following:

   a. Direction to the PAH, which shifts work emphasis between work areas or tasks, requires pursuit of certain lines of inquiry, fills in details or otherwise serves to accomplish the objectives described in the statement of work;
   b. Guidelines to the PAH that assist in the interpretation of drawings, specifications or technical portions of work description.
   c. Review and, where required by the Project Agreement, approval of technical reports, drawings, specifications, or technical information to be delivered by the PAH under the Project Agreement.

   The AOR shall monitor the PAH's performance with respect to compliance with the technical requirements of the Project Agreement.

(2) Technical direction must be within the general scope of work stated in the Project Agreement. Technical direction may not be used to
   a. Assign additional work under the Project Agreement;

b. Increase or decrease the estimated Project Agreement cost, fee (if any), or the time required for the project performance;
c. Change any of the terms, conditions or specifications of the Project Agreement; or
d. Accept non-conforming work.

As such, no verbal or written request, notice, authorization, direction or order received by the PAH shall be binding upon the MCDC, CMF or Government, or serve as the basis for a change in the Project Agreement cost or any other provision of the Project Agreement, unless issued (or confirmed) in writing by the MCDC CMF Contractual Representative designated in the Project Agreement.

(3) The PAH shall immediately notify the MCDC CMF Contractual Representative whenever a written change notification has been received from anyone other than the MCDC CMF Contractual Representative, which would affect any of the terms, conditions, cost, schedules, etc. of the Project Agreement, and the PAH is to perform no work or make any changes in response to any such notification or make any claim on the MCDC through its CMF or Government, unless the MCDC CMF Contractual Representative directs the PAH, in writing, to implement such change notification.

Article IV. AGREEMENT ADMINISTRATION

Administrative and contractual matters under this Agreement shall be referred to the following representatives of the parties:

MCDC: Advanced Technology International
MCDC Contracts
[redacted]

Project Agreement Holder: [redacted]

Each party may change its representatives named in this Article by written notification to the other parties.

Agreements Officer Representative (AOR): AOR will be designated by the Government on a per project basis.

Article V. OBLIGATION AND PAYMENT

Section 5.01 Obligation:

Except as specified in Article VII: Disputes, the CMF's liability to make payments to the PAH is limited only to those funds obligated under the Project Agreement(s). The CMF may incrementally fund the Project Agreement(s). If modification becomes necessary in performance of projects, pursuant to Article V of this Agreement, the CMF and the PAH shall establish and execute a revised Schedule of Payable Milestones consistent with the current Project Agreement.

Section 5.02 Project Payments:

The detailed instructions for project payments will be included in the Technical Direction Letter to be issued by the CMF on a project by project basis.

Section 5.03 Accounting System Requirements:

Prior to the submission of invoices, the PAH shall have and maintain an established accounting system which complies with Generally Accepted Accounting Principles (GAAP) and the requirements of this Agreement. The PAH shall ensure that appropriate arrangements have been made for receiving, distributing and accounting for Federal funds under this Agreement. Consistent with this stipulation, an acceptable accounting system will be one in which all cash receipts and disbursements are controlled and documented properly.

Section 5.04 Invoicing Instructions:

Project Payable Milestones: The PAH shall segregate and track all individual project costs separately and shall document the accomplishments of each Payable Milestone under each Project Agreement. A Payable Milestones report shall be detailed on a project basis and submitted with each request to the AOR or designee for approval.

Section 5.04 a. Payment Method Types

Project Agreements will be issued as either a fixed price milestone payment method or a cost reimbursement milestone payment method as described below.

(a) *Fixed Price Milestone Payment Method:* Payments shall be made in accordance with the Payable Milestone Schedule of each Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. The Payable Milestone Schedule may be revised as appropriate and deemed necessary by issuance of a bilateral modification to the Project Agreement. Quarterly reviews by the AOR and the CMF will assess the need for revisions to the Payable Milestone Schedule. An acceptable invoice for adjustable fixed price milestone payments is one that (on the invoice or on the Payable Milestone Report):

(i) contains the date of invoice and the Base Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone; and

(iii) lists the milestone cost negotiated and contained in each Project Agreement

(b) *Cost Reimbursable Milestone Payment Method (with not to exceed ceiling):* Payment is contingent upon satisfactory progress toward completion of milestones as delineated in Project Agreement. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. Per (ii) below, either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Project Task Assignment):

(i) contains the date of invoice and the Base Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone;

(iii) includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, and extended totals;

(iv) indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

(v) contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature _____

(c) *Cost Plus Fixed Fee Milestone Payment Method (with not to exceed ceiling):* Payment is contingent

upon satisfactory progress toward completion of milestones as delineated in Project Agreement. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. The PAH will normally fund any costs incurred above this maximum amount. Either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Project Agreement):

(i) contains the date of invoice and the Base t Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone;

(iii) includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, fixed fee and extended totals;

(iv) indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

(v) contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature _____

(d) *Cost Reimbursable, Cost Sharing Milestone Payment Method (with not to exceed ceiling):* Payment is contingent upon satisfactory progress toward completion of milestones as delineated in Project Agreement and acceptable cost share. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. Per (ii) below, either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Project Agreement):

(i) contains the date of invoice and the Base Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone;

(iii) includes a report of the cost share expended towards the accomplishment of the SOW tasks and/or milestones. This cost share report may be attached to the invoice if contractor practices make inclusion of such information on the invoice itself impractical. If the cost share report is separate from the invoice, it must be signed by an authorized representative. This cost share report must contain a breakout of the cost share by cost element similar to the level of detail required on the invoice and any in-kind contributions. The preferred method of reporting cost share is to provide an invoice for actual cost incurred with a value for the cost shared amount and the value to be reimbursed by the Government through the CMF;

(iv) includes a description of supplies and services, labor costs, subcontractor costs, material costs,

travel costs, other direct costs, and extended totals;

(v) indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

(vi) contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature _____

Section 5.04 b. Submission of Invoices

Invoices may be submitted no more frequently than monthly. The PAH shall submit invoices and any necessary supporting documentation via email to MCDC-invoices@ati.org.

For Cost type Project Agreements, the PAH's final invoice (completion invoice) will be clearly indicated as such and shall indicate the cumulative amounts incurred and billed to completion, and a written certification of the total hours expended. Actual project costs incurred and cost share performance, if applicable, of each project shall be reported and reviewed each quarter.

Section 5.04 c. Payment Terms

Payment terms are NET 30 days after CMF's receipt of an acceptable invoice. An acceptable invoice is one that meets the conditions described in Article V Section 5.04a. Payment Method Types.

Section 5.05 Advance Payments:

On a per project basis, advance payments may be approved by the AO. If the AO has approved advance payments, there will be a requirement to establish a separate interest bearing account. The PAH sets up and maintains funds in a separate interest bearing account unless one of the following applies:

(1) The PAH receives less than $120,000 in Federal awards per year;

(2) The best reasonably available interest bearing account would not expect to earn interest in excess of $250 per year on such cash advances;

(3) The depository would require an average or minimum balance so high that it would not be feasible within the expected cash resources for the project; or

(4) The advance payments are made one time to reduce financing costs for large up-front expenditures and the fund will not remain in the PAH's account for any significant period of time.

Where a separate interest bearing account is set up, any interest earned should be remitted annually to the CMF. CMF shall forward the funds to the Government as directed by the AO. Interest payments shall be made payable to the U.S. Treasury.

Section 5.06 Limitation of Funds:

Except as set forth in Article VII, the Government's financial liability will not exceed the amount obligated for projects and available for payment.

Section 5.07 Financial Records and Reports:

The PAH shall maintain adequate records to account for Federal funds received under this Agreement and shall maintain adequate records to account for Project Agreement funding provided under this Agreement, should cost sharing procedures be implemented for funding a particular project. PAH's relevant financial records are available and subject to examination or audit on behalf of the ACC-NJ for a period not to exceed five (5) years after final payment of the PAH's project. The AO or designee shall have direct access to sufficient records and information of the PAH to ensure full accountability for all funding under this Agreement. Such audit, examination or access shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited party. Any audit required during the course of the program may be conducted by the Government using Government auditors or, at the request of the PAH, by the requesting PAH's external CPA accounting firm at the expense of the requesting PAH.
AGREEMENT

Article VI. NONTRADITIONAL DEFENSE/COST SHARING

In accordance with provisions of 10 USC 2371b, Section 815 of the 2016 National Defense Authorization Act, P.L. 114-92, which provides the Department of Defense (DoD) authority to enter into transactions *other than* contracts, grants, or cooperative agreements, the Department of Defense (DoD) has the authority to make awards that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or the improvement of platforms, systems, components, or materials in use by the armed forces. Section 815 revised the definition for the term ‘nontraditional defense contractor’ as defined in Article I. Section 1.01, Definitions.

Each MCDC Member Organization must meet the definition of a Nontraditional Defense Contractor or have at least one Nontraditional Defense Contractor participating to a significant extent in the performance of an awarded Project Agreement. Examples of what might be considered a significant extent or significant contribution include, but may not be limited to supplying new key technologies or products, accomplishing a significant amount of the effort, or in some other way causing a material reduction in the cost or schedule or increase in the performance.

If significant Nontraditional Defense Contractor participation cannot be fulfilled, the Member Organization must provide at least one third cost share of the value of the Project Agreement awarded to the Member Organization. Proposals that fail to comply with this requirement will not be awarded under the OTA.

Cost Sharing is not required under this Other Transaction Agreement for projects that contain significant nontraditional defense contractor participation. Where both Parties agree, cost sharing may be considered on a per project basis under terms and conditions to be agreed to by the Parties and in accordance with the “Other Transactions” (OT) Guide For Prototype Projects dated January 2001. For traditional Government contractors without a significant nontraditional defense contractor teaming partner, a one third cost share of the project costs is required as described in the “Other Transaction” (OT) Guide For Prototype Projects dated January 2001. For traditional Government contractors with significant nontraditional defense contractor participation, cost sharing is not required for Projects under this OTA.

Throughout the period of performance of any Project Agreement, the Government AO and AOR will actively monitor Nontraditional Defense Contractor participation and/or cost sharing to ensure compliance with this provision in accordance with implementation guidance from HQDA and/or OSD. The PAH will be given the opportunity to become compliant with the guidance should they be found non-compliant. Failure to comply may result in termination.

Article VII. DISPUTES

Section 7.01 General

For the purposes of this Article, "Parties" means the CMF, the PAH and the Government where collectively identified and "Party" where each entity is individually identified. The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article.

Section 7.02 Dispute Resolution Procedures

Any disagreement, claim or dispute among the Parties concerning questions of fact or law arising from or in connection with this Agreement and whether or not involving an alleged breach of this Agreement, may be raised only under this Article.

Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable. In no event shall a dispute, disagreement or misunderstanding which arose more than three (3) months prior to the notification made under this article constitute the basis for relief under this article unless the ACC-NJ, Center Director for Emerging Technologies, in the interest of justice, waives this requirement.

Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party in writing documenting the relevant facts, identifying unresolved issues, specifying the clarification or remedy sought, and documenting the rationale as to why the clarification/remedy is appropriate. Within ten (10) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a decision by the ACC-NJ, Center Director for Emerging Technologies. The other Party shall submit a written position on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The ACC-NJ, Center Director for Emerging Technologies, will conduct a review of the matter(s) in dispute and render a decision in writing within thirty (30) calendar days of receipt of such position. Any such decision is final and binding, unless a Party shall, within thirty (30) calendar days request further review as provided by this article.

If requested within thirty (30) calendar days of the ACC-NJ, Center Director for Emerging Technologies' decision, further review will be conducted by the Chair of the MCDC Executive Committee and the ACC-NJ Associate Director. In the event of a decision, or in absence of a decision within sixty (60) calendar days of referral to the Chair of the MCDC Executive Committee and the ACC-NJ, Associate Director (or such other period as agreed to by the parties), either party may pursue any right or remedy provided by law, including but not limited to the right to seek extraordinary relief under Public Law 85-804. Alternatively, the parties may agree to explore and establish an Alternate Disputes Resolution procedure to resolve this dispute.

Section 7.03 Limitation of Liability and Damages

In no event shall the liability of the MCDC PAH or any other entity performing research activities under a Project Agreement exceed the funding such entity has received for their performance of the specific Project Agreement under which the dispute arises.

No Party shall be liable to any other Party for consequential, punitive, special and incidental damages or other indirect damages, whether arising in contract (including warranty), tort (whether or not arising from the negligence of a Party) or otherwise, except to the extent such damages are caused by a Party's willful misconduct; Notwithstanding the foregoing, claims for contribution toward third-party injury, damage, or loss are not limited, waived, released, or disclaimed.

Article VIII. CONFIDENTIAL INFORMATION

Section 8.01 Definitions

(1) "Disclosing Party" means CMF, MCDC PAHs, or the Government who discloses Confidential Information as contemplated by the subsequent Paragraphs.
(2) "Receiving Party" means CMF, MCDC PAHs, or the Government who receives Confidential Information disclosed by a Disclosing Party.
(3) "Confidential Information" means information and materials of a Disclosing Party which are designated as confidential or as a Trade Secret in writing by such Disclosing Party, whether by letter or by use of an appropriate stamp or legend, prior to or at the same time any such information or materials are disclosed by such Disclosing Party to the Receiving Party. Notwithstanding the foregoing, materials and other information which are orally, visually, or electronically disclosed by a Disclosing Party, or are disclosed in writing without an appropriate letter, stamp, or legend, shall constitute Confidential Information or a Trade Secret if such Disclosing Party, within thirty (30) calendar days after such disclosure, delivers to the Receiving Party a written document or documents describing the material or information and indicating that it is confidential or a Trade Secret, provided that any disclosure of information by the Receiving Party prior to receipt of such notice shall not constitute a breach by the Receiving Party of its obligations under this Paragraph. "Confidential Information" includes any information and materials considered a Trade Secret by the PAH. "Trade Secret" means all forms and types of financial, business, scientific, technical, economic, or engineering or otherwise proprietary information, including, but not limited to, patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if -

(a) The owner thereof has taken reasonable measures to keep such information secret; and

(b) The information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.

Section 8.02 Exchange of Information:

Neither the Government nor MCDC on behalf of the MCDC member entities or PAHs nor the CMF shall be obligated to transfer Confidential Information independently developed by the Government or the MCDC member entities or PAHs or the CMF absent an express written agreement between the Parties involved in the exchange providing the terms and conditions for such disclosure.

Section 8.03 Authorized Disclosure:

The Receiving Party agrees, to the extent permitted by law, that Confidential Information shall remain the property of the Disclosing Party (no one shall disclose unless they have the right to do so), and that, unless otherwise agreed to by the Disclosing Party, Confidential Information shall not be disclosed, divulged, or otherwise communicated by it to third parties or used by it for any purposes other than in connection with specified project efforts and the licenses granted in Article X, Patent Rights, and Article XI, Data Rights, provided that the duty to protect such "Confidential Information" and "Trade Secrets" shall not extend to materials or information that:

(a) Are received or become available without restriction to the Receiving Party under a proper, separate agreement,

(b) Are not identified with a suitable notice or legend per Article VIII entitled "Confidential Information" herein,

(c) Are lawfully in possession of the Receiving Party without such restriction to the Receiving Party at the time of disclosure thereof as demonstrated by prior written records,

(d) Are or later become part of the public domain through no fault of the Receiving Party,

(e) Are received by the Receiving Party from a third party having no obligation of confidentiality to the Disclosing Party that made the disclosure,

(f) Are developed independently by the Receiving Party without use of Confidential Information as evidenced by written records,

(g) Are required by law or regulation to be disclosed; provided, however, that the Receiving Party has provided written notice to the Disclosing Party promptly so as to enable such Disclosing Party to seek a protective order or otherwise prevent disclosure of such information.

Section 8.04 Return of Proprietary Information:

Upon the request of the Disclosing Party, the Receiving Party shall promptly return all copies and other tangible manifestations of the Confidential Information disclosed. As used in this section, tangible manifestations include human readable media as well as magnetic and digital storage media.

Section 8.05 Term:

The obligations of the Receiving Party under this Article shall continue for a period of seven (7) years from conveyance of the Confidential Information.

Section 8.06 Flow Down

The PAH shall flow down the requirements of this Article VIII to their respective personnel, member entities, agents, subawardees (including employees) at all levels, receiving such Confidential Information under this OTA.

Article IX. PUBLICATION AND ACADEMIC RIGHTS

Section 9.01 Use of Information.

For the purposes of this Article, "Parties" means the PAH and the Government where collectively identified and "Party" where each entity is individually identified.

Subject to the provisions of Article VIII, Confidential Information, Article IX, Publication and Academic Rights, and Article XI Data Rights, the PAH and the Government shall have the right to publish or otherwise disclose information and/or data developed by the Government and/or the respective MCDC PAH under the Research Project. The PAH and the Government (and its employees) shall include an appropriate acknowledgement of the sponsorship of the Research Projects by the Government and the MCDC PAH in such publication or disclosure. The Parties shall have only the right to use, disclose, and exploit any such data and Confidential Information in accordance with the rights held by them pursuant to this Agreement. Notwithstanding the above, the Parties shall not be deemed authorized by this paragraph, alone, to disclose any Confidential Information of the Government or the PAH.

Section 9.02 Publication or Public Disclosure of Information

(a) Classified Project Agreements

If a release of Confidential Information or Trade Secrets is for a classified Project Agreement, the provisions of the DoD Security Agreement (DD Form 441) and the DoD Contract Security Classification Specification (DD Form 254) apply.

(b) Review or Approval of Technical Information for Public Release.

(1) At least 30 days prior to the scheduled release date PAH shall submit to the CMF a copy of the information to be released. In turn, CMF shall submit to the Government AOR a copy of the information to be released.

The Government AOR is hereby designated as the approval authority for the AO for such releases.

(2) Where the PAH is an Academic Research Institution performing fundamental research on campus. PAH shall provide papers and publications for provision to the CMF for provision to the Government AOR for review and comment 30 days prior to formal paper/publication submission. However, if that Academic Research Institution incorporates into its research results or publications artifacts produced by and provided to these institutions on behalf of other (non-educational institution) MCDC PAHs (or has authors listed on the paper who are not employees or students of the Academic Research Institution) then the procedures in Section 9.02(a) ABOVE must be followed.

(3) Parties to this Agreement are responsible for assuring that an acknowledgment of government support will appear in any publication of any material based on or developed under this OTA, using the following acknowledgement terms:

> "Effort sponsored by the U.S. Government under Other Transaction number W15QKN-16-9-1002 between the MCDC, and the Government**.** The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

(4) Parties to this Agreement are also responsible for assuring that every publication of material based on or developed under this project contains the following disclaimer:

> "The views and conclusions contained herein are those of the authors and should not be interpreted as necessarily representing the official policies or endorsements, either expressed or implied, of the U.S. Government.

The PAH shall flowdown these requirements to its subawardees, at all tiers.

(c) Notices. To avoid disclosure of Confidential Information or Trade Secrets belonging to an MCDC member entity or PAH and/or the Government and the loss of patent rights as a result of premature public disclosure of patentable information, the PAH that is proposing to publish or disclose such information shall provide advance notice to the MCDC, through its CMF, and identify such other parties as may have an interest in such Confidential Information. The CMF shall notify such parties at least thirty (30) calendar days prior to any PAH's submission for publication or disclosure, together with any and all materials intended for publication or disclosure relating to technical reports, data, or information developed by the parties during the term of and pursuant to this Agreement. The Government must notify the MCDC, through its CMF, of any objection to disclosure within this thirty (30) day period, or else the PAH, shall be deemed authorized to make such disclosure.

(d) Filing of Patent Applications. During the course of any such thirty (30) calendar day period, the PAH shall provide notice to the CMF as to whether it desires that a patent application be filed on any invention disclosed in such materials. In the event that a PAH and/or the Government desires that such a patent be filed, the PAH or the Government proposing to publish or disclose such materials agrees to withhold publication and disclosure of such materials until the occurrence of the first of the following:

(1) Filing of a patent application covering such invention, or

(2) Written agreement, from the AO and the CMF (on behalf of the PAH to whom such Confidential Information belong) that no patentable invention is disclosed in such materials.

(3) Further, during the course of any such 90 calendar day period, the PAH shall notify the AO and the Government, through the CMF, if PAH believes any of its Confidential Information have been included in the proposed publication or disclosure and shall identify the specific Confidential Information or Trade Secrets that need to be removed from such proposed publication. The Government and the CMF on behalf of the PAH proposing the publication or disclosure of such materials agrees to remove from the proposed publication or disclosure all such Confidential Information so identified by the CMF.

Article X. PATENT RIGHTS

Section 10.01 Definitions

"Invention" means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.

"Made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

"Practical application" means to manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and in each case, under such conditions as to establish that the invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

"Subject Invention" means any invention of the MCDC's PAH or its subcontractors of any tier conceived or first actually reduced to practice in the performance of work on a Project Agreement under this Agreement.

"Background Invention" means any invention, or improvement to any invention, other than a Subject Invention, made by a PAH (or their subcontractors of any tier) that was conceived, designed, developed, produced, and/or actually reduced to practice prior to performance of the Agreement or outside the scope of work performed under this Agreement.

Section 10.02 Allocation of Principal Rights

The PAH, or its subcontractor to the extent such is proper assignee of the invention, shall retain the entire right, title, and interest throughout the world to each Subject Invention consistent with the provisions of this Article, Executive Order 12591 and 35 U.S.C § 202. In the event that a PAH consists of more than one entity or person, those entities or persons may allocate such right, title interest between themselves or others as they may agree in writing. With respect to any Subject Invention in which the PAH retains title, the Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. The PAH may elect to provide full or partial rights that it has retained to other parties. The Government shall have the right to use any products or processes used for test and evaluation (including materials for testing or assays) in any other project pursued on behalf of the U.S. Government.

Section 10.03 Invention Disclosure, Election of Title, and Filing of Patent Application

(1) The PAH shall disclose each Subject Invention to the CMF within four (4) months after the inventor discloses it in writing to his company personnel responsible for patent matters. The disclosure to the CMF shall be in the form of a written report and shall identify the Agreement under which the invention was made and the identity of the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, sale, or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure.

(2) If the PAH determines that it does not intend to retain title to any such invention, the PAH shall notify the CMF, in writing, within nine (9) months of disclosure. However, in any case where publication, sale or public use has initiated the one (1) year statutory period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by the ACC-NJ through CMF to a date that is no more than six (6) months prior to the end of the project.

(3) The PAH shall file its initial patent application on a Subject Invention to which it elects to retain title within one (1) year after election of title or, if earlier, prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use. The MCDC PAH may elect to file patent applications in additional countries (including the European Patent Office and the Patent Cooperation Treaty) within either ten (10) months of the corresponding initial patent application or six (6) months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications, where such filing has been prohibited by a Secrecy Order.

(4) After considering the position of the CMF on behalf of the PAH, a request for extension of the time for disclosure election, and filing under this Article IX, paragraph C, may be approved by ACC-NJ, which ACC-NJ approval shall not be unreasonably withheld.

Section 10.04 Conditions When the Government May Obtain Title

Upon written request to the CMF, the PAH shall convey to the Government title to any Subject Invention under any of the following conditions:

(1) If the PAH fails to disclose or elects not to retain title to the Subject Invention within the times specified in Section 10.03 of this Article X, Patent Rights; provided, that the Government may only request title within sixty (60) days after learning of the failure of the PAH to disclose or elect within the specified times.

(2) In those countries in which the PAH fails to file patent applications within the times specified in Section 10.03 of this Article X, Patent Rights; provided, that if the PAH has filed a patent application in a country after times specified in Section 10.03 of this Article X, Patent Rights, but prior to its receipt of the written request by the Government through the CMF, the PAH shall continue to retain title in that country; or

(3) In any country in which the PAH decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a patent on a Subject Invention.

Section 10.05 Minimum Rights to the MCDC PAH and Protection of the MCDC PAH's Right to File

The Parties agree that:

(1) The PAH shall retain a non-exclusive, royalty-free license throughout the world in each Subject Invention to which the Government obtains title, except if the PAH fails to disclose the invention within the times specified in Section 10.03 of this Article X, Patent Rights. PAH's license extends to the domestic (including Canada) subsidiaries and affiliates, if any, of the PAH within the corporate structure of which the PAH is a party and includes the right to grant licenses of the same scope to the extent that PAH was legally obligated to do so at the time the Project Agreement was funded. The license is transferable only with the approval of the Government, except when transferred to the successor of that part of the business to which the invention pertains. Government approval for license transfer shall not be unreasonably withheld.

(2) The PAH domestic license may be revoked or modified by the Government to the extent necessary to achieve expeditious practical application of the Subject Invention pursuant to an application for an

exclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. This license shall not be revoked in that field of use or the geographical areas in which the PAH has achieved practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of the Government to the extent the PAH, its licensees, or the subsidiaries or affiliates have failed to achieve practical application in that foreign country.

(3) Before revocation or modification of the license, the Government shall furnish the CMF, and the CMF shall forward to the PAH, a written notice of the Government's intention to revoke or modify the license, and the PAH shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

Section 10.06 Action to Protect the Government's Interest

(1) The PAH shall execute or have executed and promptly deliver to CMF all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those Subject Inventions to which the PAH elects to retain title, and (ii) convey title to the Government when requested under Section 10.04 of this Article X, Patent Rights, and to enable the Government to obtain patent protection throughout the world in that Subject Invention.

(2) The PAH agrees to require, by written agreement, that its employees working on Project Agreements, other than clerical and non-technical employees, agree to disclose promptly in writing, to personnel identified as responsible for the administration of patent matters and in a format acceptable to the CMF, each Subject Invention made under this Agreement in order that the CMF on behalf of the PAH can comply with disclosure provisions of Section 10.03 of the Article X, Patent Rights, and to execute all papers necessary to file the patent applications on the Subject Invention and to establish the Government's rights in the Subject Invention. The PAH acknowledges and shall instruct its employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The PAH shall notify the CMF of any decision not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent, in any country, not less than thirty (30) days before the expiration of the response period required by the relevant patent office.

(4) The PAH shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: "This invention was made with U.S. Government support under Agreement No. W15QKN-16-9-1002 awarded by the ACC-NJ to the MCDC. The Government has certain rights in the invention."

Section 10.07 Lower Tier Agreements

The PAH shall include the Article X, Patent Rights, suitably modified to identify the parties, in all lower tier agreements, regardless of tier, for experimental, development, or research work.

Section 10.08 Reporting on Utilization of Subject Inventions

The PAH shall submit, on request during the term of the Project Agreement, periodic reports no more frequently than annually on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the PAH or its licensees or assignees. Such reports shall include information regarding the status of development date of first commercial sale or use, gross royalties received by the PAH, and such other data and information as the agency may reasonably specify. The PAH also agrees to provide additional reports as may be requested by the Government, through CMF, in connection with any march-in proceedings undertaken by the Government in accordance with Section 10.10 of this Article X, Patent Rights. Consistent with 35 U.S.C. § 205, the Government

agrees it shall not disclose such information to persons outside the Government without permission of the MCDC on behalf of the PAHs.

Section 10.09 Preference for American Industry

Notwithstanding any other provision of the Article X, Patent Rights, the PAH is not to grant to any person the exclusive right to use or sell any Subject Invention in the United States or Canada unless such person agrees that any product embodying the Subject Invention or produced through the use of the Subject Invention shall be manufactured substantially in the United States or Canada. However, in individual cases, the requirements for such an agreement may be waived by the Government upon a showing by the PAH that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible.

Section 10.10 March-in Rights

The PAH agrees that, with respect to any Subject Invention in which its PAH has retained title, the Government, through CMF, has the right to require the PAH to obtain and grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the PAH refuses such a request, the Government has the right to grant such a licensee itself if the Government determines that:

(1) Such action is necessary because the PAH or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve practical application of the Subject Invention;

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the PAH, assignee, or their licensees;

(3) Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by the PAH, assignee, or licensees; or

(4) Such action is necessary because the Agreement required by Section 10.09 of this Article X, Patent Rights, has not been obtained or waived or because a licensee who has the exclusive right to use or sell any Subject Invention in the United States is in the breach of such Agreement.

Section 10.11 Opportunity to Cure

Certain provisions of this Article X, Patent Rights, provide that the Government may gain title or license to a Subject Invention by reason of the PAH's action, or failure to act, within the times required by this Article X, Patent Rights. Prior to claiming such rights (including any rights under Article X, Section 10.10 March-In Rights), the Government will give written notice to MCDC, through its CMF, and CMF will convey such written notice to PAH, of the Government's intent, and afford the PAH a reasonable time to cure such action or failure to act. The length of the cure period will depend on the circumstances, but in no event will be more than 60 days. PAH may also use the cure period to show good cause why the claiming of such title or right would be inconsistent with the intent of this Agreement in light of the appropriate timing for introduction of the technology in question, the relative funding and participation of the parties in the development, and other factors.

Section 10.12 Background Information

In no event shall the provisions set forth in this Article X apply to any Background Inventions or Patents. The PAHs or their subcontractors shall retain the entire right, title, and interest throughout the world to each such Inventions and Patents that each party has brought through MCDC to the project issued under this Agreement and the Government shall not have any rights under this Agreement. Projects to be funded under this Agreement will list Background Inventions and Patents anticipated to be used on the project; such listing may be amended by the parties as appropriate to reflect changes in such plans.

Section 10.13 Survival Rights

Provisions of this Article X shall survive termination of this Agreement under Article II.

Notwithstanding the terms of this Article, differing rights in patents may be negotiated among the Parties to each individual project on a case-by-case basis.

Article XI. DATA RIGHTS

This is a Data Rights Clause specifically tailored for this OTA to address respective rights of the Government and MCDC on behalf of its actual or prospective MCDC PAHs to such Data as is owned, developed, to be developed or used by an actual or prospective MCDC member entity or PAH (1) as identified in a MCDC member entity(ies) proposal submitted to the Government through the CMF in response to a competitive Government OTA call for proposals, and (2) when such proposal is selected by the Government for funded performance and the Project Agreement is issued by the CMF to that MCDC member entity for performance of such Government OTA project.

Section 11.01 Definitions

(1) "Commercial Computer Software" as used in the Article is defined in DFARS 252-227-7014(a)(1) (Jun 1995).

(2) "Commercial Computer Software License" means the license terms under which commercial computer software and Data (as defined in this OTA) is sold or offered for sale, lease or license to the general public.

(3) "Computer Data Base" as used in this Agreement, means a collection of data recorded in a form capable of being processed by a computer. The term does not include computer software.

(4) "Computer program" as used in this Agreement means a set of instructions, rules, or routines in a form that is capable of causing a computer to perform a specific operation or series of operations.

(5) "Computer software" as used in this Agreement means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae and related material that would enable the software to be reproduced, recreated or recompiled. Computer software does not include computer data bases or computer software documentation.

(6) "Computer software documentation" means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.

(7) "Data" as used in this Article of the Agreement, means computer software, computer software documentation, form, fit and function data, and technical data as defined in this Article.

(8) "Form, fit and function data" means technical data that describes the required overall physical, functional and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.

(9) "Government purpose rights" means the rights to use, modify, duplicate or disclose the "Data" licensed with such rights under this OTA within the Government for United States Government purposes only; and to release or disclose data outside the Government to any authorized persons pursuant to an executed non-disclosure agreement for such persons use, modification, or reproduction for United States Government purposes only. United States Government purposes include Foreign Military Sales purposes. Under this Agreement, the period of Government purpose rights shall be no less than ten (10) years and during such time the MCDC member entity or PAH developing or providing such Data to the Government with government purpose rights shall have the sole and exclusive right to use such Data for commercial purposes. In the event this Data is used to perform another project issued to that MCDC member entity or PAH under this OTA during this ten (10) year period, the period of

government purpose rights shall be extended an additional ten (10) years starting with the date of completion of performance of the additional project.

(10) "Limited rights" as used in this Article is as defined in DFARS 252.227-7013(a)(13) (Nov 1995).

(11) "Restricted rights" as used in this Article is as defined in DFARS 252.227-7014(a)(14) (Jun 1995).

(12) "Specially Negotiated License Rights" are those rights to Data that have been specifically negotiated between the Government and the MCDC on behalf of the member entity or PAH whose proposal is selected by the Government under a call for proposals issued under the OTA.

(13) "Technical data" means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.

(14) "Unlimited rights" as used in this Article is as defined n DFARS 252.227-7013(a)(16).

Section 11.02 Data Categories

(1) Category A is the Data developed and paid for totally by private funds, or the PAH's (or its subcontractor's) IR&D funds and it is Data to which the PAH (or its subcontractor) retains all rights. Category A Data shall include, but not be limited to,

(a) Data as defined in this Article and any designs or other material provided by the PAH for a project under this Agreement which was not developed in the performance of work under that project, and for which the PAH retains all rights.

(b) Any initial Data or technical, marketing, or financial Data provided at the onset of the project by any of the MCDC member entities or PAHs. Such Data shall be marked "Category A" and any rights to be provided to the Government for such Data under a specific project shall be as identified in the proposal submitted to the Government and included into the Technical Direction Letter and CMF issued Project Agreements.

(2) Category B is any Data developed under this OTA with mixed funding, i.e. development was accomplished partially with costs charged to a PAH's indirect cost pools and/or costs not allocated to a PAH's Project Agreement under this OTA, and partially with Government funding under this OTA. Any Data developed outside of this OTA whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subcontract shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such Data.

(3) Category C is any Data developed exclusively with Government funds under this OTA. Research and Development performed was not accomplished exclusively or partially at private expense. Under this category,

(a) the Government will have Government Purpose Rights in Data developed exclusively with Government funds under a project funded by the Government under this OTA that is:

(i) Data pertaining to an item, component, or process which has been or will be developed exclusively with Government funds;

(ii) Studies, analyses, test data, or similar data produced for this contract, when the study, analysis, test, or similar work was specified as an element of performance;

(iii) Data created in the performance of the OTA that does not require the development, manufacture, construction, or production of items, components, or processes;

(iv) Form, fit, and function data;

(v) Data necessary for installation, operation, maintenance, or training purposes (other than detailed manufacturing or process data);

(vi) Corrections or changes to technical data furnished to the Contractor by the Government;

The Government can only order such Data as is developed under the OTA project where the order request is made within one (1) year following OTA project completion. In the event the Government orders such Data, it shall pay the PAH the reasonable costs for all efforts to deliver such requested Data, including but not limited to costs of locating such Data, formatting, reproducing, shipping, and associated administrative costs.

(b) The Government shall have unlimited rights in Data

(i) Otherwise publicly available or that has been released or disclosed by PAH without restrictions on further use, release or disclosure, other than a release or disclosure resulting from the sale, transfer, or other assignment of interest in the Data to another party or the sale or transfer of some or all of a business entity or its assets to another party;

(ii) Data in which the Government has obtained unlimited rights under another Government contract or as a result of negotiations; or

(iii) Data furnished to the Government, under this or any other Government contract or subcontract thereunder, with—

(1) Government Purpose Rights or limited rights and the restrictive condition(s) has/have expired; or

(2) Government purpose rights and the PAH's exclusive right to use such Data for commercial purposes under such contract or subcontract has expired.

(c) However, any Data developed outside of this OTA whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subcontract shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such Data.

(d) Further, the Government's rights to Commercial Computer Software and Data licensed under a Commercial Computer Software License under this OTA, and the treatment of Data relating thereto, shall be as set forth in the Commercial Computer Software License.

(4) The parties to this Agreement understand and agree that the CMF shall require PAHs stamp all documents in accordance with this Article and that the Freedom of Information Act (FOIA) and Trade Secrets Act (TSA) apply to Data.

Section 11.03 Allocation of Principal Rights

(1) The Government shall have no rights to Category A Data.

(2) The Government shall have immediate Government Purpose Rights to Category B or C Data upon delivery or project or Agreement completion (whichever is earlier), except that

(a) where the PAH whose Data it is, is a small business as defined under the Small Business Innovation research Program (SBIR) under 15 U.S.C. 638, and such data was developed under a project designated by the Government in the RPP as an SBIR program project, such PAH automatically shall be entitled to a delay in the start of the Government Purpose Rights period for at least five (5) years from project completion, or such longer period as may be negotiated among the Government and MCDC on behalf of the PAH, and

(b) The CMF, at the request of small business or an other than small business MCDC member entity or PAH, may request on such member entity's or PAH's behalf a delay of the start of Government Purpose Rights in Category B or C Data for a period not to exceed five (5) years from project or Agreement completion (whichever is earlier). Such requests will only be made in those cases where the CMF has provided information from the affected actual or prospective PAH demonstrating the need for this additional restriction on Government use and shall be submitted to the ACC-NJ AO for approval, which approval shall not be unreasonably withheld. In the event of any dispute regarding approval of this request, the parties agree to treat this as a dispute and shall follow the provisions of Article VII, Disputes.

(c) for Article XI.Section 11.02 3(c) Category C Data, the Government shall have only the rights established under prior agreements.

(d) for Article XI.Section 11.02 3(d) Category C Data, the Government shall only have the rights set forth in the Commercial Computer Software Data license agreement.

(3) Data that will be delivered, furnished, or otherwise provided to the Government as specified in a specific project award funded under this Agreement, in which the Government has previously obtained rights, shall be delivered, furnished, or provided with the pre-existing rights, unless (a) the parties have agreed otherwise, or (b) any restrictions on the Government's rights to use, modify, reproduce, release, perform, display, or disclose the data have expired or no longer apply.

(4) Each proposal submitted by the MCDC member entities in response to a Government call for proposals under this OTA shall include a list of the Category A, B and C Data to be used or developed under the proposal if selected. Rights in such Data shall be as established under the terms of this Agreement, unless otherwise asserted in the proposal and agreed to by the Government. The Government AO will incorporate the list of Category A, B and C Data and the identified rights therefor in the award document.

Following issuance of a Technical Direction Letter and subsequent CMF issuance of the Project Agreement to the Government selected MCDC member entity (the PAH), the PAH shall update the list to identify any additional, previously unidentified, Data if such Data will be used or generated in the performance of the funded work. Rights in such Data shall be as established under the terms of this Agreement, unless otherwise asserted in a supplemental listing and agreed to by the Government.

Section 11.04 Marking of Data

Except for Data delivered with unlimited rights, Data to be delivered under this Agreement subject to restrictions on use, duplication or disclosure shall be marked with the following legend:

Use, duplication, or disclosure is subject to the restrictions as stated in the Agreement between the U.S. Government and the MCDC, Agreement No. W15QKN-16-9-1002, Project Title and the MCDC Project Agreement with [insert name of company] No. _____.

It is not anticipated that any Category A Data will be delivered to the Government under this Agreement.

In the event commercial computer software and Data is licensed under a commercial computer software license under this OTA, a Special License rights marking legend shall be used as agreed to by the parties.

The Government shall have unlimited rights in all unmarked Data. In the event that a PAH learns of a release to the Government of its unmarked Data that should have contained a restricted legend, the CMF on behalf of the member entity or PAH will have the opportunity to cure such omission going forward by providing written notice to the Government AO within three (3) months of the erroneous release.

Section 11.05 Copyright

The PAHs reserve the right to protect by copyright original works developed under this Agreement. All such copyrights will be in the name of the individual PAH. The PAH(s) hereby grant to the U.S. Government a non-exclusive, non-transferable, royalty-free, fully paid-up license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, for governmental purposes, any copyrighted materials developed under this agreement, and to authorize others to do so.

In the event Data is exchanged with a notice indicating that the Data is protected under copyright as a published, copyrighted work and it is also indicated on the Data that such Data existed prior to, or was produced outside of this Agreement, the Party receiving the Data and others acting on its behalf may reproduce, distribute, and prepare derivative works for the sole purpose of carrying out that Party's responsibilities under this Agreement with the written permission of the Copyright holder.

Copyrighted Data that existed or was produced outside of this Agreement and is unpublished - having only been provided under licensing agreement with restrictions on its use and disclosure - and is provided under this Agreement shall be marked as unpublished copyright in addition to the appropriate license rights legend restricting its use, and treated in accordance with such license rights legend markings restricting its use.

The PAHs are responsible for affixing appropriate markings indicating the rights of the Government on all Data delivered under this Agreement.

The Government agrees not to remove any copyright notices placed on Data and to include such notices on all reproductions of the Data.

Section 11.06 Data First Produced by the Government:

As to Data first produced by the Government in carrying out the Government's responsibilities under this OTA and which Data would embody trade secrets or would comprise commercial or financial information that is privileged or confidential if obtained from the CMF on behalf of any PAH, such Data will, to the extent permitted by law, be appropriately marked with a suitable notice or legend and maintained in confidence by the CMF and any PAH to whom disclosed for three (3) years after the development of the information, with the express understanding that during the aforesaid period such Data may be disclosed and used by the CMF or any PAH, including its respective employees or subcontractors of any tier, (under suitable protective conditions) by or on behalf of the Government for Government purposes only.

Section 11.07 Prior Technology

(1) Government Prior Technology: In the event it is necessary for the Government to furnish the CMF or any MCDC member entity or PAH, including their respective employees or their subcontractors of any tier, with Data which existed prior to, or was produced outside of this Agreement, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used only for the purpose of carrying out their responsibilities under this Agreement. Data protection will include proprietary markings and handling, and the signing of non-disclosure agreements by CMF, PAHs, PAH subcontractors of any tier and their respective employees to whom such Data is provided for use under the OTA. Upon completion of activities under this Agreement, such Data will be disposed of as requested by the Government.

(2) CMF and PAH Prior Technology: In the event it is necessary for the CMF or any PAH to furnish the Government with Data which existed prior to, or was produced outside of this Agreement, and such Data embodies trade secrets or comprises commercial or financial information which is privileged or confidential, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used by the Government and such Government Contractors or contract employees that the Government may hire on a temporary or periodic basis only for the purpose of carrying out the Government's responsibilities under this Agreement. Data protection will include proprietary markings and handling, and the signing of nondisclosure agreements by such Government Contractors or contract employees. Neither the CMF nor any PAH shall be obligated to provide Data that existed prior to, or was developed outside of this Agreement to the Government. Upon completion of activities under this Agreement, such Data will be disposed of as requested by the CMF on behalf of itself or PAHs.

(3) Oral and Visual Information: If information which the PAH (including their subcontractors of any tier and their respective employees) considers to embody trade secrets or to comprise commercial or financial information which is privileged or confidential is expressly disclosed orally or visually directly to the Government and/or CMF, the exchange of such information must be memorialized in tangible, recorded form and marked with a suitable notice or legend, and furnished to the Government and/or CMF within ten (10) calendar days after such oral or visual disclosure, or the Government and/or CMF shall have no duty to limit or restrict, and shall not incur any liability for any disclosure and use of such information. Upon Government and/or CMF request, additional detailed information about the exchange will be provided subject to restrictions on use and disclosure.

(4) Disclaimer of Liability: Notwithstanding the above, neither the Government nor the CMF shall be restricted in, nor incur any liability for, the disclosure and use of:

(a) Data not identified with a suitable notice or legend as set forth in this Article; nor

(b) Information contained in any Data for which disclosure and use is restricted under Article VIII entitled "Confidential Information" above, if such information is or becomes generally known without breach of the above, is properly known to the Government or CMF or is generated by the Government or CMF independent of carrying out responsibilities under this Agreement, is rightfully received from a third party without restriction, or is included in Data which the PAH has furnished, or is required to furnish to the Government or CMF without restriction on disclosure and use.

(5) Marking of Data: Any Data delivered under this Agreement shall be marked with a suitable notice or legend.

Notwithstanding the Paragraphs in this Article, differing rights in Data may be negotiated among the Parties to each individual project on a case-by-case basis.

Section 11.08 Lower Tier Agreements

The PAH shall include this Article, suitably modified to identify the parties, in all subcontracts or lower tier agreements, regardless of tier, or experimental, developmental, or research work.

Section 11.09 Survival Rights

Provisions of this Article shall survive termination of this Agreement under Article II.

Notwithstanding the terms of this in this Article, differing rights in data may be negotiated among the Parties to each individual Technology Project Agreement on a case-by-case basis.

Article XII. EXPORT CONTROL

Export Control

(1) Information subject to Export Control Laws/International Traffic in Arms Regulation (ITAR):

Public Law 90-629, « Arms Export Control Act, » as amended (22 U.S.C. 2751 et. seq.) requires that all unclassified technical data with military application may not be exported lawfully without an approval, authorization, or license under EO 12470 or the Arms Export Control Act and that such data require an approval, authorization, or license under EO 12470 or the Arms Export Control Act. For purposes of making this determination, the Military Critical Technologies List (MCTL) shall be used as general guidance. All documents determined to contain export controlled technical data will be marked with the following notice:

WARNING- this document contains technical data whose export is restricted by the Arms Export Control Act (Title 22, U.S.C., and Sec 2751, et seq.) or the Export Administration Act of 1979, as amended, Title 50, U.S.C., App. 2401 et seq. Violations of these export laws are subject to severe criminal penalties. Disseminate in accordance with provision of DOD Directive 5230.25.

(2) Flowdown.

The PAH shall include this Article, suitably modified, to identify all Parties, in all Project Agreements or lower tier agreements. This Article shall, in turn, be included in all sub-tier subcontracts or other forms of lower tier agreements, regardless of tier.

Article XIII. TITLE AND DISPOSITION OF PROPERTY

Section 13.01 Definitions

In this Article, "property" means any tangible personal property other than property actually consumed during the execution of work under this Agreement.

Section 13.02 Title to Property

No significant items of property are expected to be acquired under this Agreement by the PAH. Title to any item of property valued $10,000.00 or less that is acquired by the PAH pursuant to a Project Agreement with the MCDC, in performance of the project issued to the PAH under this OTA shall vest in the PAH upon acquisition with no further obligation of the Parties unless otherwise determined by the Government AO. Should any item of property with an acquisition value greater than $10,000.00 be required, the PAH through the CMF shall obtain prior written approval of the Government AO. Title to this property shall also vest in the MCDC member entity or PAH upon acquisition. That PAH shall be responsible for the maintenance, repair, protection, and preservation of all such property at its own expense. Property acquired pursuant to this clause shall not be considered as in exchange for services in performance of the project, but shall be considered a Government contribution to the project.

Section 13.03 Government Furnished Property

The Government may provide the PAH Government Furnished Property (GFP) to facilitate the performance of individual projects under this Other Transaction Agreement. Such GFP will be specifically identified to a particular project and incorporated into the applicable Project Agreement. The GFP shall be utilized only for the performance of that individual project unless a specific exception is made in writing by the Agreements Officer.

The PAH shall assume the risk of and be responsible for any loss or destruction of, or damage to, any Government Furnished Property while in its possession or control, with the exception of reasonable wear and tear or reasonable and proper consumption. All property shall be returned at the end of the Project Agreement in as good as condition as when received with the exception of said reasonable wear and tear or in accordance with the provisions of the Project Agreement regarding its use. The PAH shall obtain explicit written authorization for any transfer or disposition of Government Furnished Property.

Article XIV. CIVIL RIGHTS ACT

This Agreement and any resulting Project Agreement is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964 as amended (42 U.S.C. 2000-d) relating to nondiscrimination in Federally assisted programs. It is the responsibility of each PAH to assure the PAH has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act (Attachment 1).

Article XV. NO SMALL BUSINESS AFFILIATION

Reserved

Article XVI. ANTITRUST

In the MCDC Articles of Collaboration, members agree to comply with all applicable U.S. laws, including U.S. antitrust laws. The MCDC is recognized under the National Cooperative Research and Production Act of 1993 and the MCDC will be similarly filing under the Act.

Article XVII. SECURITY & OPSEC

All PAH shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting when applicable.

Covered Defense Information (CDI) will be identified at the Project Agreement level. The MCDC Member shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting, which includes implementing on its covered contractor information systems the security requirements specified by DFARS 252.204-7012. Nothing in this paragraph shall be interpreted to foreclose the MCDC Member's right to seek alternate means of complying with the security requirements in National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171 (as contemplated in DFARS 252.204-7008 (Compliance with Safeguarding Covered Defense Information Controls) (Oct 2016) and DFARS 252.204-7012 (Safeguarding Covered Defense Information and Cyber Incident Reporting (Oct 2016)).

Work performed by a PAH under a Project Agreement may involve access to Controlled Unclassified Information (CUI). All Controlled Unclassified Information (CUI) developed under this Agreement will be managed in accordance with DoD Manual 5200.01, Volume 4 dated February 24, 2012. Contractor personnel shall comply with applicable Technology Protection Plans (TPP), Interim Program Protection Plans (IPPP) and/or Program Protection Plans (PPP). If a project involves a Controlled Unclassified Information (CUI) effort, the below listed Department of Defense Directives, Federal Acquisition Regulation (FAR) and the Defense Federal Acquisition Regulation Supplement (DFARS), and ARDEC clauses will be incorporated into the Project Agreements by reference with the same force and effect as if they were given in full text.

(1) Each project Scope of Work will be provided by the Agreements Officer Representative (AOR) to the Joint Project Manager- Medical Countermeasure Systems Office for dissemination to the appropriate Fort Detrick COMSEC officer prior to award for review.
(2) Each project Scope of Work will be subject to Ft. Detrick policy and procedure according to DoD 5220.22-M, (National Industrial Security Program Operating Manual, NISPOM), as deemed applicable and appropriate during the security review process and prior to award. Additional COMSEC requirements may be required at other locations/facilities (based on service/command requirements).
(3) Specific applicable policies, instructions, and regulations will be identified in each project. Throughout the life of the Agreement, if any policy, instruction, or regulation is replaced or superseded, the replacement or superseding version shall apply. The following is a snapshot of key regulatory documents, policies, regulations, etc. that may be applicable at time of project award.
    a) DoDM 5200.01 DoD Information Security Program, 24 Feb 12
    b) DoD 5200.2-R Personnel Security Regulation, Jan 87
    c) DoDD 5220.22 National Industrial Security Program, 28 Feb 06
    d) DoDI 5200.01, Information Security Program and Protection of Sensitive Compartmented Information, 24 Feb 2012
    e) DoD 5400.7-R, DOD Freedom of Information Act, Sept 98
    f) DoDD 2000.12, Antiterrorism Program, 18 Aug 03
    g) FAR Clause 4.402, Safeguarding Classified Information Within Industry

h) FAR Clause 52.204-2, Security Requirements, Aug 1996

(4) For all Project Agreements, the following statement shall be flowed to the MCDC member entities unless otherwise stated within the Project Agreements.

a) Classification guidance for requirement - "The security level for this agreement is UNCLASSIFIED."

(5) Anti-Terrorism Level I Training. This provision is for PAH employees with an area of performance within an Army controlled installation, facility or area. All PAH employees requiring access to Army installations, facilities and controlled access areas shall complete AT Level I awareness training within sixty (60)-calendar- days after project start date or effective date of incorporation of this requirement into the project, whichever is applicable. PAH(s) shall submit certificates of completion for each affected employee and PAH employee, to the AOR or to the Agreements Officer, if an AOR is not assigned, within thirty (30)-calendar-days after completion of training by all employees or personnel. AT level I awareness training is available at the following website: https://atlevel1.dtic.mil/at.

(6) Access and General Protection/Security Policy and Procedures. This standard language text is for PAH employees with an area of performance within an Army controlled installation, facility or area. PAH employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The PAH also shall provide all information required for background checks to meet installation access requirements to be accomplished by installation Provost Marshal Office, Director of Emergency Services or Security Office. The PAH workforce must comply with all personal identity verification requirements as directed by DOD, HQDA and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the Force Protection Condition (FPCON) at any individual facility or installation change, the Government may require changes in PAH security matters or processes.

(7) Anti-Terrorism Awareness Training for PAH Personnel Traveling Overseas. This standard language text requires U.S.-based PAH employees to make available and to receive Government provided area of responsibility (AOR) specific AT awareness training as directed by AR 525-13. Specific AOR training content is directed by the combatant commander with the unit Anti-terrorism Officer (ATO) being the local point of contact.

(8) iWATCH Training. This standard language is for PAH employees with an area of performance within an Army- controlled installation, facility or area. PAH(s) shall brief all employees on the local iWATCH program (training standards provided by the requiring activity ATO). This local developed training will be used to inform employees of the types of behavior to watch for and instruct employees to report suspicious activity to the AOR. This training shall be completed within sixty (60)-calendar-days of a Project Agreement award and within sixty (60)-calendar- days of new employees' commencing performance with the results reported to the AOR NLT thirty (30)-calendar-days after Project Agreement award.

(9) Impact on PAH performance during increased FPCON during periods of increased threat. During FPCONs Charlie and Delta, services may be discontinued / postponed due to higher threat. Services will resume when FPCON level is reduced to Bravo or lower.

(10) Random Antiterrorism Measures Program (RAMP) participation. PAH personnel working on an installation are subject to participation in Installation RAMP security program (e.g. vehicle searches, wearing of ID badges, etc.).

(11) PAH Employees Who Require Access to Government Information Systems. All PAH employees with access to a government information system must be registered in the ATCTS (Army Training Certification Tracking System) at commencement of services, and must successfully complete the DOD Information Assurance Awareness prior to access to the IS and then annually thereafter.

(12) For projects that Require an OPSEC Standing Operating Procedure/Plan. The PAH shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within ninety (90)-calendar-days of project award to be reviewed and approved by the responsible Government OPSEC officer, per AR 530-1, Operations Security. This plan will be submitted by MCDC on behalf of the PAH(s) to the AO for coordination of approvals. This SOP/Plan will include the Government's critical information, why it needs to be protected, where it is located, who is responsible for it and how to protect it. In addition, MCDC shall identify an individual who will be an OPSEC Coordinator. MCDC will ensure this individual becomes OPSEC Level II certified per AR 530-1.

(13) For projects that Require OPSEC Training. Per AR 530-1, Operations Security, new PAH employees assigned by the PAH(s) to perform under a MCDC Project Agreement must complete Level I OPSEC awareness training within thirty (30)-calendar-days of their reporting for duty. All PAH employees performing under an OPSEC-designated project must complete annual Level I OPSEC awareness training. Level I OPSEC awareness training is available at the following website: http://cdsetrain.dtic.mil/opsec/.

(14) For Information assurance (IA)/information technology (IT) training. All PAH employees must complete the DoD IA awareness training before issuance of network access and annually thereafter. All PAH(s) working IA/IT functions must comply with DoD and Army training requirements in DoDD 8570.01, DoD 8570.01-M and AR 25-2 within six (6) months of employment.

(15) For information assurance (IA)/information technology (IT) certification. Per DoD 8570.01-M , DFARS 252.239-7001 and AR 25-2, the PAH employees supporting IA/IT functions shall be appropriately certified upon Project Agreement award. The baseline certification as stipulated in DoD 8570.01-M must be completed upon Project Agreement award.

(16) For PAH personnel authorized to accompany the Force. DFARS Clause 252.225-7040, Contractor Personnel Authorized to Accompany U.S. Armed Forces Deployed Outside the United States. The clause shall be used in projects that authorize PAH personnel to accompany U.S. Armed Forces deployed outside the U.S. in contingency operations; humanitarian or peacekeeping operations; or other military operations or exercises, when designated by the combatant commander. The clause discusses the following AT/OPSEC related topics: required compliance with laws and regulations, pre-deployment requirements, required training (per combatant command guidance) and personnel data required.

(17) For projects requiring Performance or Delivery in a Foreign Country, DFARS Clause 252.225-7043, Antiterrorism/Force Protection for Defense Contractors Outside the U.S. The clause shall be used in projects that require performance or delivery in a foreign country. This clause applies to both contingencies and non-contingency support. The key AT requirement is for non-local national PAH personnel to comply with theater clearance requirements and allows the combatant commander to exercise oversight to ensure the PAH's compliance with combatant commander and subordinate task force commander policies and directives.

(18) For projects requiring the PAH to obtain U.S. Government Common Access Cards, installation badges, and/or access passes, the PAH shall return all issued U.S. Government Common Access Cards, installation badges, and/or access passes to the AOR when the project is completed or when the PAH employee no longer requires access to the installation or facility.

(19) For projects that require access to Potential Critical Program Information (PCPI) / Critical Program Information (CPI):

a) The PAH shall comply with the associated Interim Program Protection Plan (IPPP) / Program Protection Plan (PPP) / or Technology Protection Plan (TPP). The PAH shall comply with DOD, DA and AMC technology protection requirements in DODI 5200.39, AR 70-1, DA PAM 70-3 and AMC-R-380-13.

(20) Work by the Consortium Management Firm (CMF) and Project Agreement Holder/Consortium Member (PAH) under Project Agreements may involve access to Controlled Unclassified Information (CUI) as well as information classified as "Confidential", "Secret", or "Top Secret". The CMF and the PAH and their employees who work on such Project Agreements shall comply with (1) the Security Agreement (DD Form 441), including the National Industrial Security Program Operation Manual (DOD 5220.22M), (2) any revisions to that manual that may be issued, and (3) the Agreement security classification specification (DD form 254) if included, and all security requirements including but not limited to OPSEC plans and those security requirements specific to the individual projects. During the course of this Agreement the Parties may determine that information developed by the PAH and/or the Government pursuant to this Agreement shall be treated as classified. Such information shall be classified in accordance with DOD 5220.22M.

a) Each project Scope of Work will be provided by the AOR to the AOR's local Security Office prior to award for review. For classified efforts that Security Office will provide the overall Security Classification Specification (DD Form 254). The PAH will be responsible for providing a copy of any Subcontract Security Classification Specification (DD Form 254) to lower tier awards.

b) If a Project Agreement involves a classified effort or a Controlled Unclassified Information (CUI) effort, Department of Defense Directives, Federal Acquisition Regulation (FAR) and the Defense Federal Acquisition Regulation Supplement (DFARS) clauses by reference, and local clauses will be incorporated with the same force and effect as if they were given in full text shall be incorporated into this agreement.

c) Specific applicable policies, instructions, and regulations will be identified in each Project Agreement. Throughout the life of the Project Agreement, if any policy, instruction, or regulation is replaced or superseded, the replacement or superseding version shall apply.

d) Agreement Structure

i) Research and Development under these Project Agreements will be in accordance with the Other Transaction Agreement (OTA) between the United States Army Contracting Command – New Jersey (ACC-NJ) and the MCDC in care of its Consortium Management Firm (CMF), Advanced Technology International (ATI).

ii) Within the Project Agreements, sharing of classified information will be on a need to know basis as directed in required Project Agreements.

iii) Upon Project Agreement completion or termination, the PAH must:

(1) Return ALL classified information received or generated under the Project Agreement;
(2) Destroy all of the classified information; or,
(3) Request retention for a specified period of time

Flowdown for OPSEC/Security Requirements:

MCDC shall include the aspects of this Article as they pertain to each project requirement. Each project will include specific OPSEC / Security requirements within each SOW and RPP. The requirements delineated within each project, in turn, shall be included in all sub-tier subcontracts or other forms of lower-tier agreements, regardless of tier.

Article XVIII. SAFETY

The PAH shall adhere to all local, state, and federal rules and regulations required in maintaining a safe and non-hazardous occupational environment throughout the duration of the project. At a minimum, the PAH shall provide the following reports and materials on an as needed basis:

Accident/Incident Report: The PAH shall report immediately any major accident/incident (including fire) resulting in any one or more of the following: causing one or more fatalities or one or more disabling injuries; damage of Government property exceeding $10,000; affecting program planning or production schedules; degrading the safety of equipment under a project, such as personnel injury or property damage may be involved; identifying a potential hazard requiring corrective action. The PAH shall prepare the report (DI-SAFT-81563) for each incident.

Material Safety Data Sheets (MSDS): The PAH shall prepare and maintain MSDS for all materials used and generated under this Agreement.

Environmental Requirements include the following:

Pollution Prevention: Consideration should be given to alternative materials and processes in order to eliminate, reduce, or minimize hazardous waste being generated. This is to be accomplished while minimizing item cost and risk to item performance.

Environmental Compliance: All activities must be in compliance with Federal, State, and local environmental laws and regulations, Executive orders, treaties, and agreements. The PAH shall evaluate the environmental consequences and identify the specific types and amounts of hazardous waste being generated during the conduct of efforts undertaken under this Agreement.

Hazardous Waste Report: The PAH shall evaluate the environmental consequences and identify the specific types and amounts of hazardous waste being generated during this Agreement. The PAH shall submit a Hazardous Waste Report IAW DI-MGMT-80899.

Disposal Instructions for Residual/Scrap Materials: The PAH shall dispose of all residual and scrap materials generated from this Agreement, including high explosives. The PAH shall specify the anticipated quantities, methods, and disposal costs.

Article XIX. REPRESENTATIONS AND WARRANTIES

Section 19.01 Representations and Warranties of All Parties

Each Party to this Agreement represents and warrants to the other Parties that (1) it is free to enter into this Agreement; (2) in so doing, it will not violate any other agreement to which it is a party; and (3) it has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement.

Section 19.02 Limitations

Except as expressly provided herein, no party to this Agreement makes any warranty, express or implied, either in fact or by operation of law, by statute or otherwise, relating to (1) any research conducted under this agreement, or (2) any invention conceived and/or reduced to practice under this agreement, or (3) any other intellectual property developed under this Agreement, and each party to this Agreement specifically disclaims any implied warranty of merchantability or warranty of fitness for a particular purpose.

Article XX. LIABILITY OF THE PARTIES

Section 20.01 Waiver of Liability

With regard to the activities undertaken pursuant to this Agreement, no Party shall make any claim against the others, employees of the others, the others' related entities (e.g., Government, contractors, subcontractors, etc.), or employees of the others' related entities for any injury to or death of its own employees or employees of its related entities, or for damage to or loss of its own property or that of its related entities, whether such injury, death, damage or loss arises through negligence or otherwise, except in the case of willful misconduct.

Section 20.02 Damages

The Parties shall not be liable to each other for consequential, punitive, special and incidental damages or other indirect damages, whether arising in contract (including warranty), tort (whether or not arising from the negligence of a Party) or otherwise, except to the extent such damages are caused by a Party's willful misconduct; Notwithstanding the foregoing, claims for contribution toward third-party injury, damage, or loss are not limited, waived, released, or disclaimed.

Section 20.03 Extension of Waiver of Liability

The PAH agrees to extend the waiver of liability as set forth above subawardees at any tier under an Project Agreement by requiring them, by contract or otherwise, to agree to waive all claims against the Parties to this Agreement.

Section 20.04 Applicability

Notwithstanding the other provisions of this article, this Waiver of Liability shall not be applicable to:

(1) Claims between the PAH and the CMF regarding a material breach, noncompliance, or nonpayment of funds;

(2) Claims for damage caused by willful misconduct; and

(3) Intellectual property claims.

Section 20.05 Limitation of Liability

In no case shall the CMF, or the PAH's financial liability exceed the amount obligated by the Government or committed as a Cash Contribution or In-kind Contribution by a MCDC member entity under a Project Agreement. Nothing in this Article shall be construed to create the basis of a claim or suit where none would otherwise exist.

Article XXI. GENERAL PROVISIONS

Section 21.01 Fees

The PAH will not be constrained from the payment of an appropriate fee or profit for the effort being conducted on a Project Agreement when cost share is not being contributed. The fees shall be specific to the individual Project Agreements and negotiated on project by project basis.

Section 21.02 Waiver

No waiver of any rights shall be effective unless assented to in writing by the party (Government, MCDC, CMF, or PAH) to be charged, and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

Section 21.03 Section Headings

The headings and subheadings of the sections of this Agreement are intended for convenience of reference only and are not intended to be a part of, or to affect the meaning or interpretation of this Agreement.

Section 21.04 Severability

In the event that any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement shall continue in full force and effect without said provision; Provided that no such severability shall be effective if the result of such action materially changes the economic benefit of this Agreement to the Parties.

Section 21.05 Force Majeure

No failure or omission by the CMF or the MCDC PAH in the performance of any obligation of this Agreement shall be deemed a breach of this Agreement or create any liability if the same shall arise from any cause or causes beyond the control of the Parties, including but not limited to, the following: acts of God; Acts or omissions of any Government; Any rules, regulations or orders issued by any Governmental authority or by any officer, department, and agency or instrumentality thereof; fire; storm; flood; earthquake; accident; war; rebellion; insurrection; riot; and invasion and provided that such failure or omission resulting from one of the above causes is cured as soon as is practicable after the occurrence of one or more of the above mentioned causes.

Section 21.06 Regulatory Affairs

Development and production of medical products and processes fall under the purview of the Food and Drug Administration (FDA) and research on these products involving animal or human studies is regulated by other laws, directives, and regulations. Project Awards under this Agreement that involve work in support of or related to FDA regulatory approval will address contingencies for Government access to regulatory rights in the event of product development abandonment or failure. Efforts conducted under this OTA shall be done ethically and in accordance with all applicable laws, directives, and regulations.

The Government shall ensure performance includes regulatory expertise and guidance for candidate medical countermeasure development efforts:

(1) This includes allowing the government to discuss/negotiate in partnership with the consortium how to assume appropriate risk in regulatory strategies. The government will review, negotiate, and come to consensus with the PAH on product-specific risk-based decisions.

(2) PAHs will use all regulatory programs to accelerate the pace of candidate medical countermeasure development, including fast-track status, and as appropriate meeting requirements for priority review vouchers, applying for breakthrough therapy and accelerated approval as appropriate (see FDA Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics).

(3) PAH will provide FDA submissions to the government such as all documentation requested by FDA and all proposals to FDA.

(4) PAH will allow the government to monitor all FDA communications by listening to teleconferences and attending meetings.

(5) PAH will allow the government to attend regulatory site visits and audits, and actively participate in all third-party audits.

(6) PAH will comply with Quality Assurance according to negotiated standards with the government on reports, material for Interim Fielding Capability (such as Emergency Use Authorization or Expanded Access Protocols), product for trials, prototypes, etc.

(7) PAH will provide strategies to address contingencies that could arise from regulatory directives, and regulatory failures.

Section 21.07 Radioactive Materials

PAH shall ensure compliance with the provisions of Title 10 CFR 21. This regulation establishes procedures and requirements for implementation of Section 206 of the Energy Reorganization Act of 1974.

Section 21.08 Recombinant DNA

PAH shall ensure that all work involving the use of recombinant DNA will be in compliance with guidance provided at the following website: http://www4.od.nih.gov/oba (National Institutes of Health [NIH] Guidelines for Research Involving Recombinant DNA Molecules).

Section 21.09 Required Compliance for Use of Laboratory Animals

Notwithstanding any other provisions contained in this award or incorporated by reference herein, the PAH is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the US Army Medical Research and Materiel Command, Animal Care and Use Office,. The PAH shall receive written approval to begin research under the applicable protocol proposed for a Project Agreement from the US Army Medical Research and Materiel Command, Animal Care and Use Office under separate letter to the PAH and Principal Investigator. A copy of this approval will be provided to the ACC-NJ for the official file. Non-compliance with any provision of this clause may result in the termination of award. Information is provided at the following website http://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro_regulations. The PAH will conduct advanced development/pivotal studies including human safety studies, animal efficacy studies or clinical studies required for approval using validated endpoints, and other studies as deemed necessary by the FDA for licensure of the candidate product in adherence to current Good Laboratory Practice regulations, current Good Clinical Practice regulations, and all other applicable FDA regulations in the conduct of non-clinical and clinical studies as defined by FDA guidance (21 CFR Parts 210-211).

Section 21.10 Required Compliance for Use of Human Subjects

Research under this award involving the use of human subjects may not begin until the U.S. Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol in accordance with 45 CFR Part 46. Written approval to begin research or subcontract for the use of human subjects under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the funded institution and the Principal Investigator. A copy of this approval will be provided to ACC-NJ for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award. Information is provided at the following website: http://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo.

Section 21.11 Required Compliance for use of Human Anatomical Substances

Research at funded institutions using human anatomical substances may not begin until the U.S. Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol. Written approval to begin research or subcontract for the use of human anatomical substances under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the funded institution and the Principal Investigator. A copy of this approval will be provided to ACC-NJ, from the CMF, for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award. Information is provided at the following web site: http://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo

Section 21.12 Compliance with current Good Manufacturing Processes (cGMP)

Manufacturing Standards as appropriate for the level of prototype Material used for clinical trials, pivotal non-clinical studies, consistency lots, and other uses as defined in regulatory plans should be compliant with current Good Manufacturing Processes (cGMP) as defined by FDA guidance (21 CFR Parts 210-211). If at any time during the life of the award, the PAH fails to comply with cGMP in the manufacturing, processing and packaging of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by the FDA, the PAH shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure.

Section 21.13 Registration with Select Agent Program

Where required, consortium members performing studies and tasks using select biological agent or toxins should be registered with the program with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied. Listings of select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/.

Section 21.14 Duty-Free Entry

(a) *Definitions*. As used in this clause –

(1) "Component," means any item supplied to the Government as part of an end product or of another component.
(2) "Customs territory of the United States" means the 50 States, the District of Columbia, and Puerto Rico.
(3) "Eligible product" means –
(i) "Designated country end product" as defined in the Trade Agreements clause;
(ii) "Free Trade Agreement country end product" other than a "Bahrainian end product" or a "Moroccan end product" as defined in the Buy American Act – Free Trade Agreements – Balance of Payments Program; or
(iii) "Canadian end product" as defined in Alternate I of the Buy American Act – Free Trade Agreements – Balance of Payments Program.
(4) "Qualifying country" and "qualifying country end product" have the meanings given in the Trade Agreements clause, the Buy American Act and Balance of Payments Program clause, or the Buy American Act—Free Trade Agreements—Balance of Payments Program.

(b) Except as provided in paragraph (i) of this clause, or unless supplies were imported into the customs territory of the United States before the date of a Project Agreement or the applicable subcontract, the price of this Agreement shall not include any amount for duty on-
(1) End items that are eligible products or qualifying country end products;
(2) Components (including, without limitation, raw materials and intermediate assemblies) produced or made in qualifying countries, that are to be incorporated in U.S – made end products to be delivered under an Project Agreement; or
(3) Other supplies for which the PAH estimates that duty will exceed $200 per shipment into the customs territory of the Unites States

(c) The PAH shall –
(1) Claim duty-free entry only for supplies that the PAH intends to deliver to the Government under an Project Agreement, either as end items or components of end items; and
(2) Pay duty on supplies, or any portion thereof, that are diverted to nongovernmental use, other than –
(i) Scrap or salvage; or
(ii) Competitive sale made, directed, or authorized by the Agreements Officer.

(d) Except as the PAH may otherwise agree, the Government will execute duty-free entry certificates and will afford such assistance as appropriate to obtain the duty-free entry of supplies –
(1) For which no duty is included in the Project Agreement price in accordance with paragraph (b) of this clause; and
(2) For which shipping documents bear the notation specified in paragraph (e) of this clause.

(e) For foreign supplies for which the Government will issue duty-free entry certificates in accordance with this clause, shipping documents submitted to Customs shall –
(1) Consign the shipments to the appropriate –
(i) Military department in care of the PAH, including the PAH's delivery address; or

(ii) Military installation; and

(2) Include the following information:

(i) Prime Agreement number and, if applicable, delivery order number.

(ii) Number of the subcontract for foreign supplies, if applicable.

(iii) Identification of the carrier.

(iv) (A) For direct shipments to a U.S. military installation, the notation: "UNITED STATES GOVERNMENT DEPARTMENT OF DEFENSE Duty-Free Entry to be claimed pursuant to Section XXII, Chapter 98, Subchapter VIII, Item 9808.00.30 of the Harmonized Tariff Schedule of the United States. Upon arrival of shipment at the appropriate port of entry, District Director of Customs, please release shipment under 19 CFR Part 142 and notify Commander, Defense Contract management Agency (DCMA) New York, ATTN: Customs Team, DCMAE-GNTF, 207 New York Avenue, Staten Island, New York, 10305-5013, for execution of Customs Form 7501, 7501A, or 7506 and any required duty-free entry certificates."

(B) If the shipment will be consigned to other than a military installation, e.g., a domestic contractor's plant, the shipping document notation shall be altered to include the name and address of the contractor, agent, or broker who will notify Commander, DCMA New York, for execution of the duty-free certificate. (If the shipment will be consigned to a contractor's plant and no duty-free entry certificate is required due to a trade agreement, the PAH shall claim duty-free entry under the applicable trade agreement and shall comply with the U.S. Customs Service requirements. No notification to Commander, DCMA New York, is required.)

(v) Gross weight in pounds (if freight is based on space tonnage, state cubic feet in addition to gross shipping weight.)

(vi) Estimated value in U.S. dollars.

(vii) Activity address number of the contract administration office administering the prime contract, e.g., for DCMA Dayton, S3605A.

(f) *Preparation of customs forms.*

(1)(i) Except for shipments consigned to a military installation, the PAH shall –

(A) Prepare any customs forms required for the entry of foreign supplies into the customs territory of the United States in connection with this Agreement; and

(B) Submit the completed customs forms to the District Director of Customs, with a copy to DCMA NY for execution of any required duty-free entry certificates.

(ii) Shipments consigned directly to a military installation will be released in accordance with sections 10.101 and 10.102 of the U.S. Customs regulations.

(2) For shipments containing both supplies that are to be accorded duty-free entry and supplies that are not, the PAH shall identify on the customs forms those items that are eligible for duty-free entry.

(g) The PAH shall –

(1) Prepare (if the PAH is a foreign supplier), or shall instruct the foreign supplier to prepare, a sufficient number of copies of the bill of lading (or other shipping document) so that at least two of the copies accompanying the shipment will be available for use by the District Director of Customs at the port of entry;

(2) Consign the shipment as specified in paragraph (e) of this clause; and

(3) Mark on the exterior of all packages –

(i) "UNITED STATES GOVERNMENT, DEPARTMENT OF DEFENSE"; and

(ii) The activity address number of the contract administration office administering the prime Agreement.

(h) The PAH through the MCDC CMF shall notify the ACO in writing of any purchase of eligible products of qualifying country supplies to be accorded duty-free entry, that are to be imported into the customs territory of the United States for delivery to the Government or for incorporation in end items to be delivered to the Government. The PAH through the MCDC CMF shall furnish the notice to the ACO immediately upon award to the supplier and shall include in the notice –

(1) The PAH's name, address, and Commercial and Government Entity (CAGE) code;

(2) Prime Agreement number and Project Agreement number;

(3) Total dollar value of the prime Agreement or Project Agreement number;

(4) Date of the last scheduled delivery under the prime Agreement or Project Agreement number;
(5) Foreign supplier's name and address;
(6) Number of the subcontract for foreign supplies;
(7) Total dollar value of the subcontract for foreign supplies;
(8) Date of the last scheduled delivery under the subcontract for foreign supplies;
(9) List of items purchased;
(10) An agreement that the PAH will pay duty on supplies, or any portion thereof, that are diverted to nongovernmental use other than –
  (i) Scrap of salvage; or
  (ii) Competitive sale made, directed, or authorized by the Agreements Officer;
(11) Country or origin; and
(12) Scheduled delivery date(s).

(i) This clause does not apply to purchases of eligible products or qualifying country supplies in connection with this Agreement if –
  (1) The supplies are identical in nature to supplies purchased by the PAH or any subcontractor in connection with its commercial business; and
  (2) It is not economical or feasible to account for such supplies so as to ensure that the amount of the supplies for which duty-free entry is claimed does not exceed the amount purchased in connection with this Agreement.

(j) The PAH shall –
  (1) Insert the substance of this clause, including this paragraph (j), in all subcontracts for –
    (i) Qualifying country components; or
    (ii) Nonqualifying country components for which the PAH estimates that duty will exceed $200 per unit;
  (2) Require subcontractors to include the number of this Agreement on all shipping documents submitted to Customs for supplies for which duty-free entry is claimed pursuant to this clause; and
  (3) Include in applicable subcontracts –
    (i) The name and address of the ACO for this Agreement;
    (ii) The name, address, and activity address number of the contract administration office specified in this Agreement; and
    (iii) The information required by paragraphs (h)(1), (2), and (3) of this clause.

Section 21.15 Follow-On Production

10 U.S.C. § 2371b, Section 815 authorizes the use of a follow-on production contract (FAR) or transaction (OTA). In order to be eligible for follow-on production, the following criteria is required: (1) the follow-on shall be awarded to the same participants named in the Project Agreement; (2) competitive procedures were used to award the Project Agreement in question; and (3) the Project Agreement was successfully completed. This Agreement was the result of competitive procedures, and competitive procedures are used to award individual projects under this Agreement. The Agreements Officer shall be responsible for documenting whether or not a Project Agreement was successfully completed. Follow-on production efforts shall be strictly limited to the scope of the successfully completed prototype. This Agreement will not be used to award follow-on production efforts; Government customers will be responsible for working with their contracting personnel.

All Project Agreements shall include the following statement:

"In accordance with 10 U.S.C. § 2371b(f), and upon a determination that this competitively awarded prototype project has been successfully completed, this prototype project may result in the award of a follow-on production contract or transaction without the use of competitive procedures."

Article XXII. ASSIGNMENT OF AGENCY

Section 22.01 Assignment.

Neither this Agreement nor any rights or obligations of any party hereunder shall be assigned or otherwise transferred by either party without the prior written consent of the other party.

Article XXIII. ORDER OF PRECEDENCE

In the event of any inconsistency between the general terms of this Agreement, the inconsistency shall be resolved by giving precedence in the following order: (1) the Agreement; (2) Attachments to the Agreement; (3) the Project Agreement documentation (including but not limited to the PAH proposal selected for funding by the Government). In any event, specifically negotiated Project Agreement terms will govern over general terms of this Agreement.

Article XXIV. EXECUTION

This Agreement constitutes the entire Agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Agreement may be revised only by written consent of the PAH and the CMF Contracting Representative designated in this Agreement.

Attachment I – Assurance of Compliance with Title VI of the Civil Rights Act of 1964

Statement of Assurance of Compliance with
Title VI of the Civil Rights Act of 1964
For MCDC Member Organizations

The Pfizer Inc. hereby agrees that it will comply with the provisions of the Title VI Civil Rights Act of 1964 as amended (42 U.S.C 2000-d) and all requirements imposed pursuant thereto, to the end that, in accordance with Title VI of that Act and the Regulation, no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any MCDC Project for which the MCDC member organization receives Federal financial assistance from the Government.

The MCDC member organization agrees that compliance with this assurance constitutes a condition of continued receipt of Federal financial assistance, and that it is binding upon the MCDC member organization, its successors, transferees and assignees for the period during which such assistance is provided.

The MCDC member organization further recognizes and agrees that the United States shall have the right to seek judicial enforcement of this assurance.

The person or persons whose signature(s) appear(s) below is/are authorized to sign this assurance, and commit the MCDC member organization to the above provisions.

[redacted]

_____
Signature of Authorized Official

[redacted]

_____
Title of Authorized Official

Pfizer Inc.

_____
Name of MCDC Member Organization

July 20, 2020

_____
Date